ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: April 9, 2019
Findings Date: April 9, 2019

Project Analyst: Celia C. Inman
Team Leader: Gloria C. Hale
Assistant Chief: Lisa Pittman

COMPETITIVE REVIEW

Project ID #:	J-11626-18
Facility:	Southpoint Surgery Center
FID #:	180558
County:	Durham
Applicant:	Southpoint Surgery Center, LLC
Project:	Develop a new ASC with 2 procedure rooms and 4 ORs pursuant to the need determination in the 2018 SMFP

Project ID #:	J-11631-18
Facility:	Duke North Pavilion
FID #:	956937
County:	Durham
Applicant:	Duke University Health System, Inc.
Project:	Develop 4 additional ORs pursuant to the need determination in the 2018 SMFP for a total of 69 ORs upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility,

health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C – Both Applications

Need Determination

Chapter 6 of the 2018 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional operating rooms (ORs) by service area. Application of the standard need methodology in the 2018 SMFP identifies a need for four additional ORs in the Durham County operating room service area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency): Southpoint Surgery Center, LLC, owned by North Carolina Specialty Hospital, LLC, proposing to develop four ORs in a new ambulatory surgical facility (ASF) in Durham, and Duke University Health System (DUHS) proposing to develop four additional hospital-based ORs in the existing Duke North Pavilion building in Durham. The two applicants have applied for a combined total of eight new Durham County ORs. Pursuant to the need determination in Table 6C, page 80 of the 2018 SMFP, only four new ORs may be approved in this review for the Durham County operating room service area.

Policies

There are two policies in the 2018 SMFP which are applicable to both applications in this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3, on page 33 of the 2018 SMFP, states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

Policy GEN-4, on page 33 of the 2018 SMFP, states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

Southpoint Surgery Center, LLC (SSC), "the applicant", proposes to establish a new ASF in Durham, Durham County by developing four new ORs, pursuant to the need determination in the 2018 SMFP, and two procedure rooms.

Need Determination. The applicant does not propose to develop more new ORs than are determined to be needed in the 2018 SMFP for the Durham County service area.

Policy GEN-3. The application under review is in response to the 2018 SMFP need determination for additional ORs in Durham County; therefore, Policy GEN-3 is applicable. The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, pages 11-14, Section N, pages 92-94, Section O, pages 96-98, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.3, pages 12-14, Section C.8, pages 48-50, Section L, pages 87-90, Section N, pages 92-94, and referenced exhibits. The information

provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3, pages 13-14, Section E.2, page 63, and the pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

Policy GEN-4. The proposed capital expenditure for this project is greater than $5 million; therefore, Policy GEN-4 is applicable. The applicant addresses Policy GEN-4 in Section B.3, pages 15-16, where the applicant describes its plan to implement energy efficiency and water conservation standards at the proposed facility, including, LED lighting, low volume water flow restrictors, HVAC system with energy saving controls, energy efficient windows, high value insulation, natural light, and water conserving landscaping design.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the service area; therefore, the application is consistent with the need determination in the 2018 SMFP.
- The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. Therefore, the application is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

However, the Agency determined that Project I.D. #J-11626-18 was not filed in accordance with 10A NCAC 14C .0203, which states:

"10A NCAC 14C .0203 FILING APPLICATIONS

(a) A certificate of need application shall not be reviewed by the Certificate of Need Section until it is filed in accordance with this Rule.

(b) An original and a copy of the application shall be file-stamped as received by the agency no later than 5:30 p.m. on the 15th day of the month

preceding the scheduled review period. In instances when the 15th of the month falls on a weekend or holiday, the filing deadline is 5:30 p.m. on the next business day. An application shall not be included in a scheduled review if it is not received by the agency by this deadline. Each applicant shall transmit, with the application, a fee to be determined according to the formula as stated in G.S. 131E-182(c).

(c) After an application is filed, the agency shall determine whether it is complete for review. An application shall not be considered complete if:
(1) the requisite fee has not been received by the agency; or
(2) a signed original and copy of the application have not been submitted to the agency on the appropriate application form.

(d) If the agency determines the application is not complete for review, it shall mail notice of such determination to the applicant within five business days after the application is filed and shall specify what is necessary to complete the application. If the agency determines the application is complete, it shall mail notice of such determination to the applicant prior to the beginning of the applicable review period.

(e) Information requested by the agency to complete the application must be received by the agency no later than 5:30 p.m. on the last working day before the first day of the scheduled review period. The review of an application shall commence in the next applicable review period that commences after the application has been determined to be complete."

The application was received by the Agency on November 14, 2018 for the review cycle starting December 1, 2018. The application was submitted in response to the need determination in the 2018 SMFP for four operating rooms in Durham County.

On November 20, 2018, four business days after receipt of the above referenced application, Celia Inman, Project Analyst, reviewed the application to determine if it was complete for review. Ms. Inman determined that the applicant did not calculate the fee due according to the formula stated in G.S. 131E-182(c) and that the applicant owed an additional $2,000. Therefore, the requisite fee for the application was not received by the Agency and the application was not complete for review as required by 10A NCAC 14C .0203.

On November 21, 2018, five business days after receipt of the above referenced application, the Agency mailed a letter to the contact person identified in the application, Randi Shultz, at the address specified in the application, notifying her that the application was not complete. The letter was placed in an envelope for collection and mailed following the Agency's ordinary business practices. The copy of the envelope attached to the December 4, 2018 letter indicates that the letter was postmarked on November 27, 2018, three days before the last working day before the start of the review cycle, which was Friday, November 30, 2018.

The $2,000 additional application fee due was not received by the Agency by 5:30 p.m. on Friday, November 30, 2018 as required by 10A NCAC 14C .0203. The applicant attempted to deliver a check for $2,000 after 5 p.m. on Monday, December 3, 2018, but the Agency did not accept the check since it was after the deadline for its receipt. Because the Agency did not receive the information it requested by 5:30 p.m. on Friday, November 30, 2018, the above referenced application is not complete for review as required by 10A NCAC 14C .0203 and cannot be included in the review cycle which began December 1, 2018.

Duke University Health System, Inc. (DUHS), "the applicant", proposes to add four additional ORs at DUH, License #H0015, by developing four new hospital-based ambulatory surgical ORs at Duke North Pavilion (DNP), "the facility", pursuant to the Durham County service area need determination in the 2018 SMFP. DNP is located at 2400 Pratt Street, Durham. The facility ID is FID #956937. Upon completion of the proposed project, DUH would be licensed for a total of 69 ORs, including one trauma/burn OR.

Need Determination. The applicant does not propose to develop more new ORs than are determined to be needed in the 2018 SMFP for the Durham County service area.

Policy GEN-3. The application under review is in response to the 2018 SMFP need determination for additional ORs in Durham County; therefore, Policy GEN-3 is applicable. The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, page 12, Section N, pages 94-95, Section O, pages 97-100, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.3, page 12, Section C.8, page 40, Section L, pages 86-90, Section N, page 95, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3, page 12, Section E.2, pages 52-54, Section N, pages 93-94, and the pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

Policy GEN-4. The proposed capital expenditure for this project is greater than $5 million; therefore, Policy GEN-4 is applicable. In Exhibit B.4., page 13, the applicant describes the plan to assure improved energy efficiency and water conservation,

referencing the Architect's letter in Exhibit 7, which acknowledges that the upfit of shell space and renovation of existing space will be energy efficient and in compliance with the building code and water conserving standards.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the service area; therefore, the application is consistent with the need determination in the 2018 SMFP.
- The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. Therefore, the application is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Decision

The applications submitted by the two applicants are conforming to the need determination. Both applications are conforming to the applicable policies in the 2018 SMFP. The limit on the number of ORs that can be approved is four. Collectively, the applicants propose a total of eight ORs. Therefore, both applications cannot be approved even though both are fully conforming to this criterion. See the Conclusion following the Comparative Analysis for the decision.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C – Both Applications

The 2018 SMFP shows a need for four additional ORs in Durham County. Table 6A of the 2018 SMFP, page 65, provides the current total number of ORs in Durham County, as shown below.

Facility	Inpatient ORs*	Ambulatory ORs	Shared ORs	CON Adjustments	Total*
James E. Davis Ambulatory Surgical Center (DASC)	0	8	0	0	8
Duke University Hospital	6	9	50	0	65
Duke Regional Hospital (DRH)	2	0	13	0	15
Duke University Health System	8	17	63	0	88
North Carolina Specialty Hospital	0	0	4	0	4
Durham County Total	**8**	**17**	**67**	**0**	**92**

*Number of ORs includes one trauma/burn OR at DUH and two C-Section ORs at DRH

Table 6B of the 2018 SMFP, page 73, provides the projected need determination for additional ORs in Durham County, assuming the Durham County projected population growth factor between 2016 and 2020 of 6.75, as shown below.

Facility	Total Adjusted Estimated Surgical Hours	Projected Surgical Hours for 2020*	Projected ORs Required 2020**	Adjusted Planning Inventory^	Projected OR Deficit/ Surplus(-)	Service Area Need
James E. Davis Ambulatory Surgical Center	5,370	5,732	4.37	8	(3.63)	
Duke University Hospital	6	136,051	69.77	64	5.77	
Duke Regional Hospital	2	21,160	12.06	13	(0.94)	
Duke University Health System			86.19	85	1.19	
North Carolina Specialty Hospital	0	9,886	6.59	4	2.59	
Durham County Total					**3.78**	**4**

*Assumes the projected surgical hours will grow at the Durham County population growth rate of 6.75% between 2016 and 2020
**Projected ORs required equals projected surgical hours x standard hours per OR per year, based on group assignment for each facility (Group and standard hours per OR for each facility are shown in Table 6A)
^Adjusted planning inventory excludes one trauma/burn OR at DUH and two C-Section ORs at DRH
Totals may not sum due to rounding

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms. In Section C.1, pages 17-19, the applicant describes the proposed project as follows:

"Southpoint Surgery Center proposes to develop a multispecialty ambulatory surgical facility with four operating rooms and two procedure rooms. No GI endoscopy rooms are proposed.

…

Southpoint Surgery Center offers patients and physicians a new choice of surgical provider in Durham County. The facility will be Medicare-certified and accredited by the Accreditation Association for Ambulatory Health Care (AAAHC)."

The applicant further discusses the specialties and procedures to be provided in the ORs and procedure rooms and the hours of operation at the proposed ASF on pages 17-18. Surgical specialties to be provided in the ORs include:

- General surgery – hernia repair, breast biopsy, excision of lesion, and gall bladder removal;
- Gynecology – minimally invasive procedures;
- Orthopedic – shoulder, elbow, arthroscopic knee, spine, hand, foot and ankle surgeries;
- Ophthalmology – cataract, refractive and glaucoma procedures;
- Otolaryngology – biopsies, tonsillectomy/adenoidectomy, myingtotomy, septoplasty, other sinus surgery and tympanoplasty;
- Oral and maxillofacial – extractions, implants and other maxillofacial procedures;
- Plastic surgery and cosmetic cases;
- Urology – vasectomy reversals, circumcision, incontinence, and cystoscopy procedures;
- Pain management cases involving implants; and
- Vascular cases – AV fistula creation, maintenance of vascular accesses for dialysis, and minimally invasive procedures for treating peripheral artery disease and venous disease.

The applicant proposes to provide at least three of the specialty areas listed in §131E-176(15a) to qualify its program as a "multispecialty ambulatory surgical program". N.C. Gen. Stat. §131E-176(15a) states:

"Multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."

Surgical specialties to be provided in the proposed procedure rooms include minimally invasive orthopedic, otolaryngology, ophthalmology, oral extractions, pain management, podiatry, urology, and vascular procedures.

In Section A.1(e), page 5, the applicant states that North Carolina Specialty Hospital, LLC has ownership of Southpoint Surgery Center, LLC. In Section A.9-10, pages 8-10, the applicant discusses SSC's relationship with existing surgery providers. The applicant states that the proposed SSC will have an operating agreement with Surgery Partners, which has ownership in North Carolina Specialty Hospital. Surgery Partners is a large and fast growing surgical service provider, with more than 180 locations in 32 states, including ambulatory surgical facilities and surgical hospitals. The applicant states that Surgery Partners owns and operates two ambulatory surgical facilities and one hospital in North Carolina: Orthopaedic Surgery Center of Asheville, Wilmington SurgCare, and North Carolina Specialty Hospital.

Patient Origin

On page 57, the 2018 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 62 of the 2018 SMFP, Durham County is shown as a single-county operating room service area. Thus, in this application, the service area is Durham County. Providers may serve residents of counties not included in their service area.

In Section C.1, pages 20-22, the applicant states that SSC is a new legal entity that has no historical patient origin data. The applicant provides the historical patient origin data for ORs and procedure rooms for NCSH, which has common ownership with SSC. NCSH has four ORs and five procedure rooms and the applicant expects to shift some ambulatory surgery cases from NCSH to the proposed ASF. NCSH's FY2017 (October 1, 2016 – September 30, 2017) patient origin, as shown on pages 21-22 and reported on NCSH's 2018 License Renewal Application (LRA), is summarized below.

NCSH Patient Origin
FY2017

County	OR Patients		Procedure Room Patients	
	# of Patients	% of Total	# of Patients	% of Total
Durham	1,561	41.9%	1,260	41.7%
Wake	541	14.5%	396	13.1%
Orange	415	11.1%	416	13.8%
Granville	271	7.3%	242	8.0%
Person	187	5.0%	216	7.2%
Alamance	148	4.0%	104	3.4%
Vance	68	1.8%	49	1.6%
Chatham	66	1.8%	68	2.3%
Other NC Counties*	313	8.4%	173	5.7%
Other States	154	4.1%	97	3.2%
TOTAL	**3,724**	**100.0%**	**3,021**	**100.0%**

*Other includes Ashe, Beaufort, Bertie, Brunswick, Buncombe, Cabarrus, Carteret, Caswell, Catawba, Columbus, Craven, Cumberland, Dare, Edgecombe, Forsyth, Franklin, Gaston, Guilford, Harnett, Halifax, Hertford, Johnston, Jones, Lee, Lenoir, Mecklenburg, Moore, Nash, New Hanover, Northampton, Onslow, Pender, Pitt, Perquimans, Randolph, Robeson, Rockingham, Sampson, Stanly, Warren, Wayne, and Wilson Counties.
Totals may not sum due to rounding

In Section C.3, pages 24-25, the applicant provides the projected patient origin for ORs and procedure rooms, by number of patients and percentage, for the proposed facility for the first three operating years (CY2021-CY2023), as summarized in the following tables.

Southpoint Surgery Center Projected Patient Origin
Operating Rooms

County	PY1 CY2021		PY2 CY2022		PY3 CY2023	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Durham	1,647	41.9%	1,756	41.9%	1,791	41.9%
Wake	571	14.5%	609	14.5%	621	14.5%
Orange	438	11.1%	467	11.1%	476	11.1%
Granville	286	7.3%	305	7.3%	311	7.3%
Person	197	5.0%	210	5.0%	215	5.0%
Alamance	156	4.0%	166	4.0%	170	4.0%
Vance	72	1.8%	76	1.8%	78	1.8%
Chatham	70	1.8%	74	1.8%	76	1.8%
Other NC Counties*	327	8.4%	349	8.4%	360	8.4%
Other States	162	4.1%	173	4.1%	176	4.1%
TOTAL	**3,929**	**100.0%**	**4,189**	**100.00%**	**4,273**	**100.0%**

*Other includes Ashe, Bertie, Brunswick, Buncombe, Cabarrus, Carteret, Catawba, Columbus, Craven, Cumberland, Dare, Edgecombe, Forsyth, Franklin, Gaston, Guilford, Harnett, Hertford, Johnston, Jones, Lenoir, Mecklenburg, Moore, Nash, New Hanover, Northampton, Onslow, Pender, Pitt, Perquimans, Randolph, Robeson, Rockingham, Sampson, Stanly, Warren, Wayne, and Wilson Counties.
Totals may not sum due to rounding

Southpoint Surgery Center Projected Patient Origin
Procedure Rooms

County	PY1 CY2021		PY2 CY2022		PY3 CY2023	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Durham	1,235	41.7%	1,260	41.7%	1,285	41.7%
Wake	388	13.1%	396	13.1%	404	13.1%
Orange	408	13.8%	416	13.8%	424	13.8%
Granville	237	8.0%	242	8.0%	247	8.0%
Person	212	7.1%	216	7.1%	220	7.1%
Alamance	102	3.4%	104	3.4%	106	3.4%
Vance	48	1.6%	49	1.6%	50	1.6%
Chatham	67	2.3%	68	2.3%	69	2.3%
Other NC Counties*	173	5.7%	173	5.7%	173	5.7%
Other States	95	3.2%	97	3.2%	99	3.2%
TOTAL	**2,962**	**100.0%**	**3,021**	**100.0%**	**3,081**	**100.0%**

*Other includes Ashe, Brunswick, Cabarrus, Carteret, Caswell, Columbus, Craven, Cumberland, Edgecombe, Forsyth, Gaston, Guilford, Harnett, Halifax, Hertford, Johnston, Lee, Mecklenburg, Moore, Nash, New Hanover, Northampton, Onslow, Pender, Pitt, Perquimans, Randolph, Robeson, Rockingham, Sampson, Stanly, Warren, Wayne, and Wilson Counties.
Totals may not sum due to rounding

As shown in the tables above, the applicant projects 42% of its total surgical OR and procedure room patients will originate from Durham County, with 11% to 14% of its total patients originating from Wake and Orange counties, and less than 10% of the total patients originating from Granville, Person, Alamance, Vance and Chatham counties.

In Section C, page 23, the applicant states that the above projections are based on the historical patient origin data for NCSH as provided in its 2018 LRA. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 26, the applicant states that the need for the proposed project is based on the following factors:

- the projected growth and aging of the population in Durham and neighboring counties (pages 27-28),
- increasing demand due to advances in surgical technology and anesthesia techniques (page 29),
- changes in reimbursement, cost savings and patient choice for freestanding ambulatory surgery centers (pages 30-32),
- the historical and projected growth of ambulatory surgery services in Durham County (pages 33-38),
- utilization based on physician support letters and a "reasonable and conservative" methodology and assumptions which are consistent with the OR methodology in the 2018 SMFP (pages 39-43),

- the need for positive competition and increased choice of a new provider in the Durham County market (page 44).

The information provided in the sections as noted above is reasonable and adequately supported for the following reasons:

- The applicant adequately documents that the growing and aging Durham County population, particularly those over age 65, will continue to utilize healthcare services, supporting future increase in demand for ambulatory surgery services.
- The applicant adequately documents that changes in surgical and anesthesia techniques, including use of fiber optics, miniature video cameras and special surgical instruments handled via tubes and surgical microscopes, support the continued shift of surgical procedures to the ambulatory setting.
- The applicant adequately documents that changes in reimbursement, cost savings and patient choice for freestanding ambulatory surgery centers have influenced the increase in demand for ambulatory surgical services.
- The applicant adequately documents the need for additional ambulatory ORs by documenting the historical North Carolina ambulatory surgical cases as a percent of total surgical cases as compared to that of Durham County. The applicant provides information relative to the surgical procedures performed at NCSH and NCSH's need to shift ambulatory cases to the proposed ASF.
- The applicant adequately demonstrates continued growth in the NCSH medical staff and its planned recruitment, as well as the physician support for its proposed four OR project, providing documentation of physician support letters with annual estimates for surgical volume.
- The applicant adequately demonstrates that the proposed project offers patients and physicians a new freestanding, non-hospital based ambulatory surgical facility in Durham County, which could create positive competition and have a positive impact on Durham County surgical services. However, SSC has common ownership with NCSH and therefore is not a "new provider" of surgical services in Durham County, though it could be considered a new provider of non-hospital based ambulatory surgical services.

Projected Utilization

In Section Q, Form C, page 110, the applicant provides projected utilization for the proposed ORs, as illustrated in the following table. (Note that the Project Analyst refers to the Section Q page numbers as listed on the bottom right corner of the pages, rather than the upper right corner.)

SSC
Operating Room Projected Utilization

	Last FFY (Proposed New ASF)	1st Full FY CY2021	2nd Full FY CY2022	3rd Full FY CY2023
Adjusted Planning Inventory (1)	NA	4	4	4
Standard Hours per OR per Year (2)	NA	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	NA	NA	NA	NA
Final Inpatient Case Time (3)	NA	NA	NA	NA
Inpatient Surgical Hours (4)	NA	NA	NA	NA
Ambulatory Surgical Cases	NA	3,929	4,189	4,273
Final Ambulatory Case Time (3)	NA	68.6	68.6	68.6
Ambulatory Surgical Hours (4)	NA	4,492	4,789	4,885
Total Surgical Hours (5)	NA	4,492	4,789	4,885
# of ORs Needed (6)	NA	3.4	3.6	3.7
# of ORs Needed (rounded)	NA	3	4	4

(1) Last Full FY – proposed new facility. The first three full FYs includes the proposed OR(s).
(2) From Page 59 in the 2018 SMFP, Group 6.
(3) From Page 59 in the 2018 SMFP in minutes.
(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Methodology and Assumptions, pages 103-106, the applicant provides the assumptions and methodology used to project operating room utilization, which is summarized below:

- Step 1, page 103
  Project NCSH OR utilization, using a 2% annual growth rate based upon population growth and aging, patient satisfaction, physician recruitment, physician support with documented projected surgical volumes, and the implementation of the facility's emergency department.

NCSH Projected Utilization

	Interim FY2016	Interim FY2017	Interim FY2018	Interim CY2019	Interim CY2020	PY1 CY2021	PY2 CY2022	PY3 CY2023
# of ORs	4	4	4	4	4	4	4	4
Inpatient Cases	1,629	1,649	1,528	1,559	1,590	1,622	1,654	1,687
Ambulatory Cases	3,606	3,724	3,344	3,411	3,479	3,549	3,620	3,692

- Step 2, page 103
  Calculate the expected shift of ambulatory surgery OR cases from NCSH to SSC at 60% for PY1 and 65% for PY2 and PY3.

	PY1 CY2021	PY2 CY2022	PY3 CY2023
NCSH Inpatient Cases	1,622	1,654	1,687
NCSH Ambulatory Cases	3,549	3,620	3,692
Percent Ambulatory Cases to Shift to SSC	60%	65%	65%
Ambulatory Cases Expected to Shift to SSC	2,129	2,353	2,400
NCSH Inpatient Cases	1,622	1,654	1,687
NCSH Ambulatory Cases after Shift	1,419	1,267	1,292

- Step 3, page 103
  Calculate the annual surgical hours for NCSH based on the 2018 SMFP methodology and assumptions and Step 2 shift of cases.

NCSH Surgical Hours
Applicant's Calculation in Step 3

	PY1 CY2021	PY2 CY2022	PY3 CY2023
NCSH Inpatient Cases	1,785	1,821	1,857
NCSH Ambulatory Cases	1,612	1,439	1,468
Inpatient Case Time	141.9	141.9	141.9
Ambulatory Case Time	90.0	90.0	90.0
NCSH Inpatient Surgical Hours	4,222	4,307	4,392
NCSH Ambulatory Surgical Hours	2,418	2,159	2,202
Total Surgical Hours	6,640	6,464	6,594

However, as can be seen in a comparison of the final number of NCSH inpatient and ambulatory surgical cases after the shift in cases to SSC, the applicant does not use the number of cases calculated in Step 2 to begin its Step 3 calculations. The Project Analyst performs the same calculation as the applicant in Step 3, but begins the calculation with the NCSH inpatient and ambulatory cases calculated in Step 2, after the shift of ambulatory cases to SSC, as shown below.

NCSH Surgical Hours
Project Analyst's Calculation of Step 3

	PY1 CY2021	PY2 CY2022	PY3 CY2023
NCSH Inpatient Cases	1,622	1,654	1,687
NCSH Ambulatory Cases	1,419	1,267	1,292
Inpatient Case Time	141.9	141.9	141.9
Ambulatory Case Time	90.0	90.0	90.0
NCSH Inpatient Surgical Hours	3,836	3,912	3,990
NCSH Ambulatory Surgical Hours	2,129	1,901	1,938
Total Surgical Hours	5,965	5,811	5,928

Difference in Applicant's and Project Analyst's
Calculation of Step 3

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Total Surgical Hours - Applicant	6,640	6,464	6,594
Total Surgical Hours – Project Analyst	5,965	5,811	5,928
Applicant's Over-projection of Surgical Hours at NCSH after Shift	675	653	666

- Step 4, page 104
  Calculate number of ORs needed based on number of annual surgical hours projected in accordance with the Group 4 assignment in the 2018 SMFP; the applicant's table on page 104 uses its incorrectly calculated figures from Step 3 and 1,500 hours per OR and calculates the need for 4.4, 4.3, and 4.4 ORs in project years (PY) 1 through 3, respectively. However, the Project Analyst calculates the need for 4.0, 3.9, and 4.0 ORs in PY1 through PY3, respectively, using the correctly calculated surgical hours in Step 3, as shown below.

Project Analyst's Calculation of Step 4
Using Correct Surgical Hours from Step 3

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Total Surgical Hours – Project Analyst	5,965	5,811	5,928
Annual Hours per OR	1,500	1,500	1,500
ORs Needed	4.0	3.9	4.0

As the table above shows, using the applicant's methodology and assumptions and the correctly calculated cases and hours from Step 3, NCSH still shows a need for four ORs.

- Step 5 , page 104
  Project SSC OR and procedure room (PR) utilization based solely on the proposed recruitment of 25 new surgeons prior to 2021, performing 72 OR cases and 32 PR cases per surgeon in PY1, with an annual growth rate of 2%.

Projected SSC OR and PR Utilization
By Newly Recruited Surgeons Only

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Projected OR Cases by New Surgeons	1,800	1,836	1,873
Projected PR Cases by New Surgeons	800	816	832

Assumptions: New Surgeons = 25
OR Cases per Surgeon = 72
PR Cases per Surgeon = 32
Annual Growth Rate = 2%

- Step 6, page 104
  Project SSC OR utilization based on the proposed shift of ambulatory cases from NCSH in Step 2. Combine the projected cases from the new surgeons, as calculated in Step 5 above.

Projected SSC OR Utilization

	PY1 CY2021	PY2 CY2022	PY3 CY2023
OR Cases Projected to Shift from NCSH to SSC in Step 2	2,129	2,353	2,400
Projected OR Cases by New Surgeons	1,800	1,836	1,873
Total Projected OR Cases	3,929	4,189	4,273

- Step 7, page 104
  Calculate the annual surgical hours based on the 2018 SMFP assigned Group 6 average case time of 68.6 minutes per case and the total cases calculated in Step 6.

Projected SSC OR Surgical Hours

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Total OR Cases (Step 6)	3,929	4,189	4,273
Average Case Time	68.6	68.6	68.6
Total Annual Surgical Hours	4,492	4,789	4,885

- Step 8, page 105
  Calculate the number of ORs needed at SSC based on the 2018 SMFP Group 6 assignment of standard hours per OR of 1,312.5.

Projected SSC OR Need

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Total Annual Surgical Hours	4,492	4,789	4,885
Standard Surgical Hours per OR (Group 6)	1,312.5	1,312.5	1,312.5
Total ORs Needed	3.4	3.6	3.7

As the table above shows, the applicant projects a need for four ORs at SSC in the second and third project years.

- Step 9, page 105
  Project PR utilization at both NCSH and SSC based on a 2% growth rate, supported by population growth, patient satisfaction, physician recruitment, and the implementation of the NCSH's emergency department. SSC's cases are based on the projected shift of 65% of cases from NCSH, in addition to the cases projected from new surgeons, as calculated in Step 5.

SSC Procedure Room Projected Utilization

	PY1 CY2021	PY2 CY2022	PY3 CY2023
NCSH Projected PR Cases Based on 2% Annual Growth	3,326	3,392	3,460
Percent to Shift top SSC	65%	65%	65%
PR Cases to Shift to SSC	2,162	2,205	2,249
PR Cases Projected from New Surgeons in Step 5	800	816	832
Total Projected PR Cases for SSC	2,962	3,021	3,081

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant bases future utilization at NCSH on historical utilization, projected forward at a 2.0% annual growth rate, which is reasonable considering the 2018 SMFP OR methodology growth factor of 6.75 for Durham County, the decrease in NCSH surgical utilization from FY2017 to FY2018, NCSH's recent loss of two physicians, NCHS's recruitment of physicians to replace the two lost and its commitment to continue recruiting physicians, the opening of the emergency department, current capacity constraints, and the shift of ambulatory cases from NCSH to the proposed ASF.
- The expected shift of OR and PR cases from NCSH to SSC is supported by capacity constraints at NCSH, access to cost-saving ambulatory surgery services, the planned recruitment of 25 new surgeons, the physician letters from current NCSH physician staff, as documented in Exhibit C.4(a), improved patient convenience, improved OR size and layout in the proposed new facility, expanded scheduling, improved access for physicians with medical offices nearby, and the convenient location for the growing county population.

In response to written comments submitted during the 30-day comment period, suggesting that outpatient surgery cases may shift away from NCSH during the interim project years due to the development of other ASF projects in adjoining counties, the applicant states:

"The comment is inaccurate because:

- *Southpoint has no other operating room projects that have been approved or are pending review in adjoining counties.*
- *NCSH has CON-exempt facility projects in development that will improve the hospital's overall capacity during the interim years that are documented in the application.*
- *Page 39 of the Southpoint application documents the medical staff growth and pending additions to the Medical staff."*

Access

In Section C.8, pages 48-50, the applicant states:

"Southpoint Surgery Center will expand access to healthcare services for the medically underserved by providing surgical procedures to patients who are indigent, lack health insurance or are otherwise medically underserved. . . . As a multi-specialty ambulatory surgical facility, Southpoint Surgery Center is committed to provide access for all payer categories of patients."

In Section L, page 89, the applicant projects the following payor mix during the second full fiscal year (FY) of operation, PY2, following completion of the project, as illustrated in the table below.

Proposed Payor Mix
PY2 CY2022

Payor Source	Entire Facility	Operating Rooms	Procedure Room
Self-Pay	1.0%	0.7%	1.5%
Charity Care	0.4%	0.3%	0.5%
Medicare *	47.4%	47.0%	48.0%
Medicaid *	3.4%	3.0%	4.0%
Insurance *	41.6%	42.0%	41.0%
Workers Compensation	4.6%	5.0%	4.0%
TRICARE	1.6%	2.0%	1.0%
Other	0.0%	0.0%	0.0%
Total	**100.0%**	**100.0%**	**100.0%**

* Including any managed care plans
Totals may not sum due to rounding

The proposed project does not involve GI endoscopy rooms. The applicant states on page 89 that the projected payor mix is based on 2017 historical payor percentages for NCSH

ambulatory OR cases. The proposed ASF is not an existing facility; however, SSC and NCSH have common ownership and management, and some existing surgical cases will shift to the proposed facility from NCSH. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served for all the reasons discussed above.
- The applicant adequately explains why the population to be served needs the services proposed in this application for all the reasons discussed above.
- Projected utilization is reasonable and adequately supported for all the reasons discussed above.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions for all the reasons discussed above.

However, pursuant to 10A NCAC 14C .0203, this application cannot be included in the review period beginning December 1, 2018 because the Agency determined that the application was not complete by November 30, 2018, the last working day before the review began. Therefore, Project ID #J-11626-18 is not approvable in this review. The discussion regarding 10A NCAC 14C .0203 in Criterion (1) is incorporated herein by reference.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP. The following DUHS entities are part of the DUHS "health system", as defined by the 2018 SMFP, and provide surgical services in the Durham County OR service area:

- DUH,
- James E. Davis Ambulatory Surgical Center (DASC), and
- Duke Regional Hospital (DRH).

The 2018 SMFP provides the total number of DUHS ORs in Durham County, as reported on the facilities' 2017 LRAs and summarized below.

Facility	Inpatient ORs*	Ambulatory ORs	Shared ORs	CON Adjustments	Total*
DASC	0	8	0	0	8
DUH	6	9	50	0	65
DRH	2	0	13	0	15
DUHS Total	**8**	**17**	**63**	**0**	**88**

*Number of ORs includes one trauma/burn OR at DUH and two C-Section ORs at DRH. For purposes of calculating a need determination for additional ORs, the 2018 SMFP OR methodology excludes one trauma/burn OR at DUH and two C-Section ORs at DRH for a total of 64 ORs at DUH and 13 ORs at DRH and a total of 85 ORs in the DUHS.

As shown above, DUHS has eight inpatient ORs in Durham County, including one trauma/burn OR and two C-Section ORs, per the 2018 SMFP. The 2018 LRA for DUH reports seven inpatient ORs, nine ambulatory ORs and 49 Shared ORs for a total of 65 ORs. The 2018 LRA reports one more inpatient OR and one less shared OR than the 2017 LRA for the same total number of ORs. The applicant uses the number of ORs as reported on its 2018 LRA and reflected in the Proposed 2019 SMFP in its discussion of its ORs and the need for additional ORs. The applicant also includes Arringdon ASC (AASC), a DUHS CON application (Project ID #J-11508-18) approved in September 2018 to develop a new ASF by relocating four ORs from DASC to the proposed AASC facility, in its discussion of projected need and utilization of ORs.

In Section C.1, page 14, the applicant states that the proposed project does not involve development of new services or reduction of any services, but rather will expand DUH's surgical OR capacity to accommodate growing surgical volumes. The applicant further states:

> *"Pursuant to an exemption notice dated August 27, 2018, Duke University School of Medicine has undertaken a renovation and expansion of the North Pavilion building that currently houses academic space and clinical space leased to DUHS. Please see Exhibit 3 for a copy of the exemption letter approval from the Healthcare Planning and Certificate of Need Section. This expansion provides the opportunity for DUHS to upfit available space to make expanded surgical services readily available in a cost effective and efficient manner."*

Patient Origin

On page 57, the 2018 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 62 of the 2018 SMFP, Durham County is shown as a single-county operating room service area. Thus, in this application, the service area is Durham County. Providers may serve residents of counties not included in their service area.

In Section C.2, page 15, the applicant provides the historical patient origin, by number of patients and percentage of total, for DUH's last full fiscal year, FY2018 (July 1, 2017-June 30, 2018), as summarized below.

Duke University Hospital Surgical Cases
Patient Origin by County
FY2018

	Inpatient		Outpatient	
County	**Patients**	**Percent of Total**	**Patients**	**Percent of Total**
Durham	3,610	19.7%	5,380	23.9%
Wake	2,544	13.9%	3,844	17.1%
Orange	647	3.5%	1,379	6.1%
Alamance	693	3.8%	846	3.8%
Person	591	3.2%	787	3.5%
Granville	617	3.4%	674	3.0%
Cumberland	528	2.9%	573	2.5%
Guilford	345	1.9%	459	2.0%
Vance	424	2.3%	350	1.6%
Johnston	250	1.4%	285	1.3%
Franklin	199	1.1%	230	1.0%
Chatham	115	0.6%	231	1.0%
Harnett	252	1.4%	216	1.0%
Other States	2,801	15.3%	2,389	10.6%
Other NC Counties*	4,709	25.7%	4,866	21.6%
Total	**18,325**	**100.0%**	**22,509**	**100.0%**

Totals may not sum due to rounding
Source: DUHS Finance
*Other NC counties includes less than one percent of patients from each of the remaining counties in North Carolina
Note: Consistent with the reporting of patients in license renewal applications, the total number of surgical cases is equivalent to the total number of patients.

In Section C.3, pages 16-18, the applicant provides the projected patient origin, by number of patients and percentage, for the first three operating years (FY2022-FY2024), as summarized in the following tables.

Duke University Hospital Surgical Cases
Patient Origin by County
FY2022

	Inpatient		Outpatient	
County	**Patients**	**Percent of Total**	**Patients**	**Percent of Total**
Durham	3,910	19.7%	5,037	23.9%
Wake	2,755	13.9%	3,599	17.1%
Orange	701	3.5%	1,291	6.1%
Alamance	751	3.8%	792	3.8%
Person	640	3.2%	737	3.5%
Granville	668	3.4%	631	3.0%
Cumberland	572	2.9%	537	2.5%
Guilford	374	1.9%	430	2.0%
Vance	459	2.3%	328	1.6%
Johnston	271	1.4%	267	1.3%
Franklin	216	1.1%	215	1.0%
Chatham	125	0.6%	216	1.0%
Harnett	273	1.4%	202	1.0%
Other States	3,034	15.3%	2,237	10.6%
Other NC Counties*	5,100	25.7%	4,556	21.6%
Total	**19,847**	**100.0%**	**21,076**	**100.0%**

Totals may not sum due to rounding
Source: DUHS Finance
*Other NC counties includes less than one percent of patients from each of the remaining counties in North Carolina
Note: Consistent with the reporting of patients in license renewal applications, the total number of surgical cases is equivalent to the total number of patients.

Duke University Hospital Surgical Cases
Patient Origin by County
FY2023

	Inpatient		Outpatient	
County	**Patients**	**Percent of Total**	**Patients**	**Percent of Total**
Durham	3,989	19.7%	4,930	23.9%
Wake	2,811	13.9%	3,523	17.1%
Orange	715	3.5%	1,264	6.1%
Alamance	766	3.8%	775	3.8%
Person	653	3.2%	721	3.5%
Granville	682	3.4%	618	3.0%
Cumberland	583	2.9%	525	2.5%
Guilford	381	1.9%	421	2.0%
Vance	468	2.3%	321	1.6%
Johnston	276	1.4%	261	1.3%
Franklin	220	1.1%	211	1.0%
Chatham	127	0.6%	212	1.0%
Harnett	278	1.4%	198	1.0%
Other States	3,095	15.3%	2,189	10.6%
Other NC Counties*	5,203	25.7%	4,459	21.6%
Total	**20,246**	**100.0%**	**20,628**	**100.0%**

Totals may not sum due to rounding
Source: DUHS Finance
*Other NC counties includes less than one percent of patients from each of the remaining counties in North Carolina
Note: Consistent with the reporting of patients in license renewal applications, the total number of surgical cases is equivalent to the total number of patients.

Duke University Hospital Surgical Cases
Patient Origin by County
FY2024

	Inpatient		Outpatient	
County	**Patients**	**Percent of Total**	**Patients**	**Percent of Total**
Durham	4,069	19.7%	4,884	23.9%
Wake	2,867	13.9%	3,490	17.1%
Orange	729	3.5%	1,252	6.1%
Alamance	781	3.8%	768	3.8%
Person	666	3.2%	714	3.5%
Granville	695	3.4%	612	3.0%
Cumberland	595	2.9%	520	2.5%
Guilford	389	1.9%	417	2.0%
Vance	478	2.3%	318	1.6%
Johnston	282	1.4%	259	1.3%
Franklin	224	1.1%	209	1.0%
Chatham	130	0.6%	210	1.0%
Harnett	284	1.4%	196	1.0%
Other States	3,157	15.3%	2,169	10.6%
Other NC Counties*	5,308	25.7%	4,417	21.6%
Total	**20,654**	**100.0%**	**20,434**	**100.0%**

Totals may not sum due to rounding
Source: DUHS Finance
*Other NC counties includes less than one percent of patients from each of the remaining counties in North Carolina
Note: Consistent with the reporting of patients in license renewal applications, the total number of surgical cases is equivalent to the total number of patients.

In Section C, page 19, the applicant states that the above patient origin is based upon DUH's historical inpatient and ambulatory surgery patient origin; and significant changes are not anticipated. The applicant also provides detailed steps for the projection in Section Q.

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 20-35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 20, the applicant states:

> *"According to Table 6B of the 2018 SMFP, DUH is projected to have a deficit of 5.77 ORs in 2020 based on the standard methodology for projecting operating*

room need. Similarly, the Table 6B of the Proposed 2019 SMFP projects DUH to have a deficit of 5.98 ORs in 2021 based on the standard methodology for projecting operating room need."

As shown in the 2018 SMFP, Table 6B, page 73, DUH shows a need for 5.77 ORs and the Duke University Health System shows a need for 1.19 total ORs. The need methodology in the 2018 SMFP excludes the one trauma/burn OR at DUH for a total of 64 ORs and the two C-Section ORs at DRH for a total of 13 ORs. DUH has 16 licensed ORs approved under Policy AC-3 (CON Project ID #J-8030-07), which are included in the count of ORs in the need methodology.

Beginning on page 20 of the application, the applicant states that the need for the proposed project is supported by the following:

- growing inpatient volumes at DUH (pages 20-23),
- growing number of inpatient discharges treated at academic medical centers and teaching hospitals in North Carolina (pages 23-24),
- growing ambulatory surgical volumes at DUHS and DUH (pages 24-26),
- ongoing facility expansion projects at DUH (pages 26-27),
- physician recruitment plans (pages 27-28), and
- projected population growth in the service area (pages 28-35).

The information provided by the applicant in the sections noted above is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for additional ORs at DUH based on the 2018 SMFP OR need methodology.
- The applicant adequately documents that inpatient surgical volume at DUH grew steadily from FY2014 through FY2018, at a 2.0% compound annual growth rate (CAGR) and inpatient discharges grew at a 4-year CAGR of 2.9% between FY2013 and FY2017.
- The applicant adequately demonstrates that while inpatient discharges in North Carolina have declined by 1% since 2010, the volume of inpatient discharges treated at academic medical centers and teaching hospitals has risen by 7.4%.
- The applicant adequately demonstrates that in total, DUHS's ambulatory surgical utilization has increased by a CAGR of 4.8% between FY2014 and FY2018; that DUH's ambulatory surgical case volume and case time continue to grow in the face of capacity constraints within DUH's existing surgical platform; and that the continued shift of surgical procedures from inpatient to outpatient settings will contribute to future ongoing demand for outpatient surgery at Duke.
- The applicant adequately demonstrates that the ongoing expansion at the North Pavilion building provides the opportunity for DUHS to upfit available space to make expanded surgical services available in a cost effective and efficient manner; and the OR addition will develop needed capacity to accommodate DUH's growing demand for ambulatory surgery, shifting demand from the existing shared

ORs located in Duke North and the Duke Medical Pavilion to the expanded ambulatory surgical suite at DNP.

- The applicant adequately demonstrates that the DUH primary and secondary service area population continues to grow and age, which will continue to support the ongoing demand for inpatient and ambulatory surgical services at DUH.

In response to written comments submitted during the 30-day public comment period, the applicant states:

> *"The four-year CAGR for DUH's outpatient surgical cases may be lower compared to DUH's four-year CAGR for inpatient surgical cases; however, this is in no way due to a comparatively lower demand for outpatient surgical cases. As described in Section C of DUH's CON application, Duke has made significant efforts to facilitate the shift in surgical volumes to other facilities, resulting in an increase in outpatient procedures at other facilities in the system. Even with these efforts, however, demand for outpatient procedures at DUH has not decreased significantly and inpatient procedures continue to grow at the hospital. Even with potential shift of outpatient procedures to Arringdon – which was limited to those procedures that could be done in an ASC rather than a hospital – there is high utilization of outpatient services* <u>*and*</u> [emphasis in original] *inpatient services at DUH.*
>
> *The development of 90 additional acute care beds and the resulting ability to admit additional patients for inpatient services will generate even greater demand for inpatient surgical services at DUH. As set forth in the application, expanded surgical access at North Pavilion will enable DUH to decant ambulatory surgical demand from the existing shared ORs located in Duke North and the Duke Medical Pavilion (DMP) to the expanded ambulatory surgical suite at the North Pavilion thereby expanding access for inpatient surgical services. For information purposes, current surgical procedures routinely performed at North Pavilion identified in the public comments are a reflection not of structural limitations but rather just of existing scheduling, equipment, and staffing practices based on existing capacity and need.*
>
> *As an academic medical center with highly specialized services, Duke will always face a demand for highly specialized services that need to be performed at the hospital, and it accordingly has a significant deficit of ORs. It is not feasible or efficient to duplicate all of the professional and support staff and clinical resources that would* [sic] *necessary to provide the same specialized services at multiple facilities. Therefore, regardless of current or projected utilization at other facilities, DUH will continue to have a need for additional OR capacity at the hospital."*

Projected Utilization

In Section Q, beginning on page 105, the applicant provides the methodology and assumptions for its projected utilization for DUHS, the Duke "health system" in Durham County, and for the proposed project's first three years of operation following completion of the project. The applicant's table in Section Q, DUH Form C, includes the one trauma/burn OR, which the 2018 SMFP excludes from the OR methodology. Therefore, the applicant's table shows 65 as the total number of ORs, while the 2018 SMFP, page 73, shows the adjusted planning inventory for DUH as 64. The following table summarizes the applicant's information in Section Q Form C, but excludes one trauma/burn OR, which the 2018 SMFP excludes from the OR methodology, resulting in the Adjusted Planning Inventory of 64 ORs for FY2016, as shown in the 2018 SMFP, and 68 in project years FY2022 through FY2024, after the addition of the proposed four ORs.

DUH
Operating Room Utilization

	Prior Full Fiscal Year FY2016	**1st Full FY FY2022 7/21-6/22**	**2nd Full FY FY2023 7/22-6/23**	**3rd Full FY FY2024 7/23-6/24**
Adjusted Planning Inventory (1)	64	68	68	68
Standard Hours per OR per Year (2)	1,950	1,950	1,950	1,950
Inpatient Surgical Cases	17,151	19,847	20,246	20,654
Final Inpatient Case Time (3)	267.7	267.7	267.7	267.7
Inpatient Surgical Hours (4)	76,522	88,549	90,333	92,152
Ambulatory Surgical Cases	22,642	21,076	20,628	20,434
Final Ambulatory Case Time (3)	135.0	135.0	135.0	135.0
Ambulatory Surgical Hours (4)	50,945	47,420	46,413	45,976
Total Surgical Hours (5)	127,467	135,969	136,746	138,128
# of ORs Needed, Rounded (6)	65	70	70	71
OR Deficit / Surplus (-) Rounded	1	2	2	3

Totals may not sum due to rounding.
(1) Last Full FY2016 (7/1/15-6/30/16) is from Table 6B in the 2018 SMFP, as reported in the DUH 2017 LRA, representing FY2016. The first three full FYs includes the proposed four OR(s). The applicant's table (Form C) shows a total of 65 existing ORs and 69 for PY 1-3; the table as summarized above, excludes one Trauma/Burn OR, which is excluded per the 2018 SMFP, Table 6A, for a total of 64 existing ORs and 68 in total for PY1-3.
(2) From Table 6A in the 2018 SMFP, Group 1 (1,950).
(3) From Table 6B in the 2018 SMFP.
(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time in minutes divided 60.
(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year

The applicant also provides the projected utilization for DRH, DASC, and Arringdon ASC (AASC) (Project ID #J-11508-18) in Section Q, Form C, as summarized in the following tables and resulting in the table for projected utilization for DUHS, the Duke "health system" in Durham County. The tables, as presented below, are based on the applicant's

information in Form C, adjusted to agree with the 2018 SMFP to exclude the two C-Section ORs at Duke Regional Hospital. The tables include the proposed shift in surgical cases from DRH and DASC to AASC based on Project ID #J-11508-18.

DRH
Operating Room Utilization

	Prior Full Fiscal Year FY2016	1st Full FY FY2022 7/21-6/22	2nd Full FY FY2023 7/22-6/23	3rd Full FY FY2024 7/23-6/24
Adjusted Planning Inventory (1)	13	13	13	13
Standard Hours per OR per Year (2)	1,755	1,755	1,755	1,755
Inpatient Surgical Cases	3,765	4,665	4,803	4,945
Final Inpatient Case Time (3)	212.0	212.0	212.0	212.0
Inpatient Surgical Hours (4)	13,303	16,484	16,970	17,471
Ambulatory Surgical Cases	2,981	4,808	5,002	5,257
Final Ambulatory Case Time (3)	131.2	131.2	131.2	131.2
Ambulatory Surgical Hours (4)	6,518	10,514	10,938	11,495
Total Surgical Hours (5)	19,821	26,998	27,908	28,965
# of ORs Needed, Rounded (6)	11	15	16	17
OR Deficit / Surplus (-) Rounded	-2	2	3	4

Totals may not sum due to rounding.
(1) Last Full FY is from Table 6B in the 2018 SMFP, excludes two C-Section ORs.
(2) From Table 6A in the 2018 SMFP, Group 3 (1,755).
(3) From Table 6B in the 2018 SMFP.
(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time in minutes divided 60.
(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

DASC
Operating Room Utilization

	Prior Full Fiscal Year FY2016	1st Full FY FY2022 7/21-6/22	2nd Full FY FY2023 7/22-6/23	3rd Full FY FY2024 7/23-6/24
Adjusted Planning Inventory (1)	8	4	4	4
Standard Hours per OR per Year (2)	1,312.5	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	0	0	0	0
Final Inpatient Case Time (3)	NA	NA	NA	NA
Inpatient Surgical Hours (4)	0	0	0	0
Ambulatory Surgical Cases	5,164	7,492	7,569	8,057
Final Ambulatory Case Time (3)	62.4	62.4	62.4	62.4
Ambulatory Surgical Hours (4)	5,371	7,791	7,872	8,379
Total Surgical Hours (5)	5,371	7,791	7,872	8,379
# of ORs Needed, Rounded (6)	4	6	6	6
OR Deficit / Surplus (-) Rounded	-4	2	2	2

Totals may not sum due to rounding

(1) Last Full FY is from Table 6B in the 2018 SMFP. FY2022-2024 are based on Project ID #J-11508-18, relocating four ORs and shifting patients.

(2) From Table 6A in the 2018 SMFP, Group 5 (1312.5).

(3) From Table 6B in the 2018 SMFP.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time in minutes divided 60.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

AASC
Operating Room Utilization

	FY2021 7/20-6/21	1st Full FY FY2022 7/21-6/22	2nd Full FY FY2023 7/22-6/23	3rd Full FY FY2024 7/23-6/24
Adjusted Planning Inventory (1)	4	4	4	4
Standard Hours per OR per Year (2)	1,312.5	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	0	0	0	0
Final Inpatient Case Time (3)	NA	NA	NA	NA
Inpatient Surgical Hours (4)	0	0	0	0
Ambulatory Surgical Cases (1)	2,733	3,737	4,936	4,936
Final Ambulatory Case Time (3)	68.6	68.6	68.6	68.6
Ambulatory Surgical Hours (4)	3,125	4,273	5,643	5,643
Total Surgical Hours (5)	3,125	4,273	5,643	5,643
# of ORs Needed, Rounded (6)	2	3	4	4
OR Deficit / Surplus (-) Rounded	-2	-1	0	0

Totals may not sum due to rounding
(1) FY2022-FY2024 from projected utilization in Project ID #J-11508-18. Cases for FY2024 held constant at FY2023 numbers.
(2) From Project ID #J-11508-18 and methodology in 2018 SMFP, Group 6 (1312.5).
(3) From Project ID #J-11508-18 and methodology in 2018 SMFP.
(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time in minutes divided 60.
(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

DUHS in Durham County
Operating Room Utilization

	Prior Full Fiscal Year FY2016	1st Full FY FY2022 7/21-6/22	2nd Full FY FY2023 7/22-6/23	3rd Full FY FY2024 7/23-6/24
Adjusted Planning Inventory (1)	85	89	89	89
Total Surgical Hours (2)	152,659	175,030	178,170	181,115
# of ORs Needed, Rounded (2)	81	94	96	98
OR Deficit / Surplus (-) Rounded	-4	5	7	9

Totals may not sum due to rounding.
(1) Last Full FY2016 (7/1/15-6/30/16) is from Table 6B in the 2018 SMFP, as reported in the DUH 2017 LRA, representing FY2016; however, excluding one trauma/burn OR at DUH and two C-Section ORs at DRH. The first three full FYs includes the proposed OR(s).
(2) Sum of the total surgical hours for each facility table above.

In Section Q, Form C Assumptions, pages 105-114, the applicant provides the assumptions and methodology used to project operating room utilization, which is summarized below:

- DUHS' fiscal year is July 1 through June 30. The project begins July 1, 2021. PY1 is the first full fiscal year July 1, 2021 through June 30, 2022, FY2022.
- Review historical DUHS surgical cases and growth rates (pages 106-108)

	FY2014	FY2015	FY2016	FY2017	FY2018	4-Yr CAGR
DASC (Outpatient)	4,406	4,869	5,164	5,277	7,645	14.8%
DUH (Inpatient)	16,920	17,344	17,151	17,989	18,325	2.0%
DUH (Outpatient)	22,292	23,728	22,642	22,575	22,509	0.2%
DUH Total	39,212	41,072	39,793	40,564	40,834	1.0%
DRH (Inpatient)	3,697	3,865	3,765	4,539	4,153	3.0%
DRH (Outpatient)	2,899	2,995	2,981	3,352	3,992	8.3%
DRH Total	6,596	6,860	6,746	7,891	8,145	5.4%

Totals may not sum due to rounding

- Determine projected surgical growth rate to project future surgical volume at DUHS (pages 108-109)

	Growth Rates	Growth Rate Assumption
DASC (Outpatient)	5.0%	4-Yr CAGR capped at 5%
DUH (Inpatient)	2.0%	4-Yr CAGR
DUH (Outpatient)	0.2% 1.0%	4-Yr CAGR during interim years; 1.0% annually during PY1-PY3
DRH (Inpatient)	3.0%	4-Yr CAGR
DRH (Outpatient)	5.0%	4-Yr CAGR capped at 5%

- Project DUHS inpatient and outpatient OR cases prior to shifting any cases

	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
DASC (Outpatient)	7,645	8,027	8,429	8,850	9,293	9,757	10,245
DUH (Inpatient)	18,325	18,694	19,071	19,455	19,847	20,246	20,654
DUH (Outpatient)	22,509	22,564	22,618	22,673	22,900	23,129	23,360
DUH Total	40,834	41,258	41,689	42,128	42,747	43,375	44,014
DRH (Inpatient)	4,153	4,276	4,402	4,532	4,665	4,803	4,945
DRH (Outpatient)	3,992	4,192	4,401	4,621	4,852	5,095	5,350
DRH Total	8,145	8,467	8,803	9,153	9,518	9,898	10,294

Totals may not sum due to rounding

- Determine DUHS projected shift in cases to AASC and Green Level ASC (page 111-113)

  The following table summarizes the outpatient surgical cases projected to shift to AASC based on the methodology described in CON Project ID #J-11508-18.

DUHS ASC-Appropriate Cases Projected to Shift to AASC

	FY2021	FY2022	FY2023	FY2024
Shift from DASC	1,446	1,801	2,188	2,188
Shift from DUH	1,159	1,623	2,090	2,090
Shift from DRH	0	44	93	93
Shift from Duke Raleigh Hospital (DRAH)	128	269	565	565
Total	2,733	3,737	4,936	4,936

Totals may not sum due to rounding
Source: CON Project ID #J-11508-18

The following table summarizes the outpatient surgical cases projected to shift to from DUHS facilities to Green Level ASC based on the methodology described in CON Project ID #J-11557-18.

DUHS ASC-Appropriate Cases Projected to Shift to Green Level ASC

	FY2022	FY2023	FY2024
Shift from DASC	0	0	0
Shift from DUH	201	411	836
Shift from DRH	0	0	0
Shift from DRAH	2,077	2,916	3,933
Total	2,278	3,327	4,770

Totals may not sum due to rounding
Source: CON Project ID #J-11557-18

The following table combines the shift of surgical cases from DUHS to AASC and Green Level ASC.

DUHS Cases Projected to Shift to AASC and Green Level ASC

	FY2021	FY2022	FY2023	FY2024
Shift from DASC	1,446	1,801	2,188	2,188
Shift from DUH	1,159	1,824	2,501	2,926
Shift from DRH	0	44	93	93
Shift from DRAH	128	2,346	3,481	4,498
Total	2,733	6,015	8,263	9,706

Totals may not sum due to rounding

- Project surgical cases at DUHS Durham County facilities after shifts of cases to AASC and Green Level ASC (page 113)

	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
DASC (Outpatient)	7,645	8,027	8,429	7,404	7,492	7,569	8,057
DUH (Inpatient)	18,325	18,694	19,071	19,455	19,847	20,246	20,654
DUH (Outpatient)	22,509	22,564	22,618	21,514	21,076	20,628	20,434
DUH Total	40,834	41,258	41,689	40,969	40,922	40,874	41,088
DRH (Inpatient)	4,153	4,276	4,402	4,532	4,665	4,803	4,945
DRH (Outpatient)	3,992	4,192	4,401	4,621	4,808	5,002	5,257
DRH Total	8,145	8,467	8,803	9,153	9,474	9,805	10,201

Totals may not sum due to rounding

- Projected DUHS Durham County PY3 (FY2024) OR Need (page 114)

	OR Group	Hours/ OR/ Year	Case Time	FY2024 Surgical Cases	FY2024 Surgical Hours	Surgical ORs Required	2024 ORs Inventory*	2024 ORs Needed
AASC (Outpt)	6	1312.5	68.6	4,936	5,643	4.3	4	0.3
DASC (Outpt)	5	1312.5	62.4	8,057	8,379	6.4	4	2.4
DUH (Inpt)			267.7	20,654	92,152			
DUH (Outpt)			135.0	20,434	45,976			
DUH Total	1	1950.0			138,128	70.8	68	2.8
DRH (Inpt)			212.0	4,945	17,471			
DRH (Outpt)			131.2	5,257	11,495			
DRH Total	3	1755.0			28,965	16.5	13	3.5

Totals may not sum due to rounding
*2024 OR inventory includes the proposed four ORs at DUH and excludes one trauma/burn OR at DUH and two C-Section ORs at DRH, per the 2018 SMFP

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant bases future utilization on historical utilization,
- the applicant uses inpatient growth rates based on historical growth rates,
- the applicant uses outpatient growth rates based on historical growth rates, capped in the cases of DASC and DRH; and increased by 0.8% during the proposed project years in the case of DUH to adjust for the expansion of the hospital-based ambulatory surgery platform at DNP and the relief of capacity constraints,
- the applicant uses the appropriate OR Group, minutes per case, and standard hours per OR for utilization projections, and
- the growing and aging population, statistical data regarding surgical procedures, the development of 90 additional acute care beds at DUH, Duke physician recruitment plans, and letters of support from Duke surgeons.

Access

In Section C.8, page 40, the applicant states:

"All area residents, including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups, will have access to the proposed additional DUH operating rooms, as clinically appropriate. DUHS does not discriminate on the basis of race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided in Exhibit 6."

In Section L, page 89, the applicant projects the payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the table below.

Proposed Payor Mix
FY2023

Payor Source	Inpatient Surgery	Outpatient Surgery
Self-Pay/Charity Care	2.1%	2.4%
Medicare *	43.7%	35.6%
Medicaid *	17.8%	9.7%
Insurance *	30.4%	47.1%
Other (Workers comp, VA & TRICARE)	6.2%	5.2%
Total	**100.0%**	**100.0%**

* Including any managed care plans
Totals may not sum due to rounding

The applicant states that the projected payor mix is based on the historical payor mix of inpatient and outpatient surgical cases at DUH, adjusted for a slight shift from managed care to Medicare. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served for all the reasons discussed above.

- The applicant adequately demonstrates the need the population to be served has for the proposed project for all the reasons discussed above.
- Projected utilization is based on reasonable and adequately supported assumptions for all the reasons discussed above.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions for all the reasons discussed above.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

Neither applicant proposes to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to the review of their applications.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section E, pages 62-63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- maintain the status quo – the applicant states that this is not an effective long-term alternative due to the extraordinarily high utilization of the ORs at NCSH, the fact that NCSH is nearing its maximum practical capacity, and the fact that increases in inpatient surgery utilization are expected to continue.
- develop a smaller ASF with two ORs – the applicant states that this is not an effective alternative because developing a new facility with only two ORs would be too limited to accommodate both the shift of cases from NCSH and the projected utilization of the proposed new surgeons, would not accommodate the increased utilization of more complex orthopedic and spine cases, and would not be as cost effective as a facility with four or more ORs, which have greater economies of scale.

- develop the project as proposed – the applicant states that this alternative is the most effective alternative for the following reasons:

    - The project will maximize patient access, support the growth of the medical staff, and achieve high utilization.
    - The project will provide a broad array of surgical specialties.
    - The project will accommodate the continued growth in ambulatory surgery utilization for the population of Durham and high growth counties.
    - The project will provide for greater scheduling capacity.
    - The project will expand patient access to cost-effective operating room capacity.
    - The project will achieve economies of scale, support highly competitive facility charges, and offer cost savings to patients.

The applicant provides supporting documentation in Section C and Exhibits C.3 and C.4. The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the applicant's identified need for the following reasons:

- Maintaining the status quo is not an effective option due to the high demand for surgical services at NCSH and the capacity constraints at NCSH.
- A facility with only two ORs would not accommodate the shift of ambulatory surgery cases from NCSH and the sizable number of surgical cases projected for the proposed surgeon recruitment. Also a facility with only two ORs would likely have scheduling constraints.
- Developing an ASF with four ORs and two procedure rooms would be the most effective alternative, providing enhanced access for physicians and patients, cost-effective services, and economies of scale.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new ambulatory surgical ORs at DNP. The total number of ORs in the Duke University Health System in Durham County would be 98, including one trauma/burn and two C-Section ORS (69 ORs at DUH, 15 ORs at DRH, four ORs at DASC and four ORs at AASC, assuming completion of this project and Project ID #J-11508-18).

In Section E, pages 52-54, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Status quo, pursue no additional ORs – the applicant states that this alternative is not an effective alternative based on growing surgical demand at DUH for both inpatient and outpatient surgical services; and given that the 2018 SMFP projects DUH to have a deficit of 5.77 ORs in 2020.
- Develop four ORs at DRH – the applicant states that DUH is a full-service tertiary and quaternary care hospital and Academic Medical Center, while DRH is a community hospital; therefore DUH serves a different patient population compared to DRH. The applicant also states that the 2018 SMFP standard methodology for projecting ORs projects DUH to have a deficit of 5.77 ORs in 2020. The applicant further states that DUHS determined that developing the ORs at DUH is the more effective alternative for enhancing access to surgical services at this time.
- Develop four ORs as a new freestanding ASF – the applicant states its belief that the redistribution of existing ORs from DASC to AASC (Project ID #J-11508-18) will enhance geographic access to freestanding ASF services in Durham County; therefore, the proposed project was determined to be more effective.

On page 54, the applicant states:

> *"Upon review of DUH's historical and projected inpatients and outpatient surgical utilization and consideration of DUHS's recently approved CON application to develop a freestanding ASC in Durham County, the proposed project was determined to be the most effective alternative."*

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the applicant's identified need for the following reasons:

- The 2018 SMFP identified need for surgical services in Durham County shows DUH will have a 5.77 OR deficit in 2020.
- The development of additional ORs at DUH will reduce the projected 2020 deficit at DUH.
- The development of the project as proposed will allow DUHS to meet the expected continued growth of DUH's inpatient and ambulatory surgical cases and continue to enhance its provision of specialized acute care services.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, page 113, the applicant states the total capital cost is projected to be as follows:

SSC Project Capital Cost

Construction Costs	$	5,500,000
Medical Equipment	$	4,157,900
Miscellaneous	$	2,408,730
TOTAL CAPITAL COST	**$**	**12,066,630**

In Section Q, page 113, the applicant provides the assumptions used to project the capital cost.

Exhibit F.1 contains the construction cost estimate prepared by a North Carolina licensed architect, as shown in the table above, and a detailed listing of the proposed equipment costs.

In Section F.3, pages 65-66, the applicant projects that start-up costs will be $150,000 and initial operating expenses will be $600,000, for total working capital required of $750,000.

On page 66, the applicant also provides the assumptions used to project the working capital costs.

Availability of Funds

In Section F, page 64, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Southpoint Surgery Center, LLC
Loans	$ 12,066,630
Accumulated reserves or OE *	
Bonds	
Other (Specify)	
Total Financing	**$ 12,066,630**

* OE = Owner's Equity

In Section F, page 67, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	$ 750,000
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	
(c)	Lines of credit	
(d)	Bonds	
(e)	**Total**	**$ 750,000**

Exhibit F-2 contains letters from First Citizens Bank documenting intent to provide financing for the capital and working capital needs for the proposed project. Also provided in the exhibit is the NCSH FY2017 Operating Statement and Balance Sheet. The amortization worksheet for the two loans from First Citizens Bank is provided in Section Q, page 127 of the application.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3 Revenues and Operating Expenses, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the Project Analyst's table below.

Southpoint Surgery Center ASF

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Total Surgical Cases	3,929	4,189	4,273
Total Gross Revenues (Charges)	$33,319,682	$36,586,432	$38,437,706
Total Net Revenue	$11,488,626	$12,615,002	$13,253,321
Average Net Revenue per Surgical Case	$2,924	$3,011	$3,102
Total Procedure Room (PR) Cases	2,962	3,021	3,081
Total Gross PR Revenues (Charges)	$12,557,976	$13,193,410	$13,860,996
Total Net PR Revenue	$3,003,868	$3,155,864	$3,315,550
Average Net Revenue per Procedure	$1,014	$1,045	$1,076
Total Cases/Procedures	6,891	7,210	7,354
Total Gross Revenue	$45,877,658	$49,779,842	$52,298,702
Total Contractual Adjustments*	$31,385,164	$34,008,977	$35,729,831
Total Net Revenue	$14,492,494	$15,770,865	$16,568,871
Average Net Revenue per Case	$2,103	$2,187	$2,253
Total Operating Expenses (Costs)	$13,509,795	$14,211,555	$14,720,984
Average Operating Expense per Case	$1,961	$1,971	$2,002
Net Income	$982,699	$1,559,310	$1,847,887

Totals may not sum due to rounding
* Includes Charity Care and Bad Debt as follows:

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Charity Care	$162,749	$175,726	$184,618
Bad Debt	$458,777	$497,798	$522,987

As shown in the table above, the project has a net income of $1.5 million and $1.8 million in project years two and three, respectively.

Written comments submitted during the 30-day public comment period called the financial feasibility of the project into question based on the percent fee for the management agreement, the projected $20,000 financing cost, and the $50,000 interest during construction. In its response to comments, the applicant states that the management agreement was clearly marked "For Discussion Purposes Only" and that the management fee percentage and amount in the pro forma financials are accurate and have been reviewed and certified by the applicant. The applicant further states that *"Form 1.a includes a $590,000 budgeted line item for contingency amount. This contingency amount can be allocated to any other line item of the total CON capital expenditure and far exceeds the amounts that DUH alleges are understated and unreasonable."* Furthermore, the net income of $982,699, $1,559,310, and $1,847,887 in the first three operating years, respectively, will cover the minor difference in the percent management fee each year.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the

application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new ambulatory surgical ORs at DNP.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant states the total capital cost is projected to be as follows:

DUHS Project Capital Cost

Construction/Renovation Contract	$	7,003,766
Architect/Engineering Fees	$	1,194,300
Medical Equipment	$	7,231,650
Miscellaneous	$	1,770,284
TOTAL CAPITAL COST	**$**	**17,200,000**

In Section Q, the applicant provides the assumptions used to project the capital cost. Exhibit 7 contains the cost certification letter, verifying the projected cost as shown in the table above.

In Section F.3, page 58, the applicant states that as an expansion of an existing service, there are no start-up costs or initial operating expenses associated with the project.

Availability of Funds

In Section F.2, page 56, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DUHS	Total
Loans		
Accumulated reserves or OE *	$17,200,000	$17,200,000
Bonds		
Other (Specify)		
Total Financing	**$17,200,000**	**$17,200,000**

* OE = Owner's Equity

Exhibit 9 contains a letter from DUHS' Chief Financial Officer committing up to $20 million accumulated cash reserves for the capital costs of the proposed project. DUHS' June 30, 2018 audited financial statement (Exhibit 9) shows cash and cash equivalents of $277,957,000, total current assets of $1,269,102,000 and total net assets of $3,619,728,000.

Financial Feasibility

The applicant provides pro forma financial statements for the DUH ORs and for DUHS, as a system, for the first three full fiscal years of operation following completion of the project. In Form F.3 Revenues and Operating Expenses for the DUH ORs, the applicant projects that operating expenses will exceed revenues in each of the first three operating years of the project, as shown in the table below.

DUH Operating Rooms

	PY1 FY2022	PY2 FY2023	PY3 FY2024
Total Surgical Cases	40,923	40,874	41,088
Total Gross Revenues (Charges)	$2,665,391,507	$2,697,342,655	$2,736,474,332
Total Contractual Adjustments*	$1,821,411,527	$1,833,705,221	$1,850,480,307
Total Net Patient Revenue	$843,979,980	$863,637,424	$885,994,025
Average Net Revenue per Case	$20,624	$21,129	$21,563
Other Revenue	$0	$0	$0
Total Revenue	$853,979,980	$863,637,424	$885,994,025
Total Operating Expenses (Costs)	$1,004,970,558	$1,046,337,746	$1,091,370,052
Average Operating Expense per Case	$24,557.60	$25,599.10	$26,561.77
Net Income	($160,990,578)	($182,700,322)	($205,376,027)

Totals may not sum due to rounding
*Includes Charity Care (gross Self-pay/CC less net self-pay/CC) as follows:

	PY1 FY2022	PY2 FY2023	PY3 FY2024
Charity Care	$56,527,754	$57,139,014	$57,921,179

However, Form F.3 Revenues and Operating Expenses for DUHS, shows that total revenues will exceed total expenses in the first three operating years of the project, as shown in the following table.

DUHS Revenues and Expenses
(In Thousands)

	PY1 FY2022	PY2 FY2023	PY3 FY2024
Total Gross Revenues (Charges)	$12,357,236	$12,780,852	$13,112,526
Total Contractual Adjustments*	$8,608,305	$8,867,486	$9,060,645
Total Net Patient Revenue	$3,748,931	$3,913,366	$4,051,881
Other Revenue	$217,457	$220,989	$224,739
Total Revenue	$3,966,388	$4,134,355	$4,276,620
Total Operating Expenses (Costs)	$3,764,354	$3,923,925	$4,059,076
Net Operating Income	$202,034	$210,430	$217,544
Non-Operating Revenue and Expense	$148,725	$162,764	$178,318
Excess Revenue over Expenses	$350,759	$373,194	$395,862

Totals may not sum due to rounding
*Includes Charity Care as follows:

	PY1 FY2022	PY2 FY2023	PY3 FY2024
Charity Care	$389,966,000	$394,609,000	$399,310,000
Bad Debt	$217,000	$221,000	$226,000

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the

application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C – Both Applications

On page 57, the 2018 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 62 of the 2018 SMFP, Durham County is shown as a single-county operating room service area. Thus, in this review, the service area is Durham County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Durham County, and the inpatient and outpatient case volumes for each provider, from pages 65 and 73 of the 2018 SMFP, respectively.

Durham County 2016 Operating Room Inventory and Cases
As Reported in the 2018 SMFP from the 2017 License Renewal Applications

	IP ORs	OP ORs	Shared ORs	Excluded C-Section/ Trauma/Burn ORs	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
James E. Davis Ambulatory Surgical Center (DASC)	0	8	0	0	0		5,164	5
Duke University Hospital	6	9	50	-1	0	17,151	22,642	1
Duke Regional Hospital	2	0	13	-2	0	3,765	2,981	3
Duke University Health System	8	17	63	-3	0			
North Carolina Specialty Hospital	0	0	4	0	0	1,629	3,606	4
Total Durham County ORs	**8**	**17**	**67**	**-3**	**0**			

Source: 2018 SMFP

As the table above indicates, there are three hospitals and one existing or approved ASF in Durham County with a total of eight inpatient, 17 ambulatory and 67 shared operating rooms, including one trauma/burn and two C-Section ORs. Project ID #J-11508-18 was approved for the development of an additional DUHS ASF in Durham County, AASC, by the relocation of four DASC ORs to the proposed facility. The total number of Durham County ORs is not changed by that project.

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section G, pages 70-71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Durham County. The applicant states:

> *"Southpoint Surgery Center proposes to develop four operating rooms in a multispecialty ambulatory surgical facility which will not result in unnecessary duplication of existing or approved facilities because 1) the proposed project does not exceed the operating room need determination in the 2018 SMFP; 2) the vast majority of operating rooms are hospital based or hospital owned; 3) NCSH has maintained high utilization and many physicians have documented their intent to shift cases to Southpoint Surgery Center; and 4) the project offers a new alternative provider to enhance patient access and deliver high quality and cost effective surgery."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for four ORs and SSC proposes four ORs.

- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs in Durham County.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

In Section G, pages 65-66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Durham County. On page 64, the applicant provides a table showing the total annual utilization during FY2017 of the existing and approved facilities that provide surgical services in Durham County. On page 65, the applicant states:

> *"The proposed project will not result in an unnecessary duplication of existing or approved facilities in Durham County. The State Health Coordinating Council has determined that Durham County has a need for an additional four operating rooms.*
>
> *…*
>
> *For information purposes, DUH surgical volume continues to generate the greatest need for additional Durham County ORs in Table 6B of the Proposed 2019 SMFP of any facility. Under the state's methodology, DUHS would need 70 total operating rooms to properly accommodate its FY2017 utilization, even without any projected growth in utilization resulting from population growth and other factors.*
>
> *The robust growth of surgical cases (both inpatient and outpatient) at DUH obviously supports the need for DUHS to develop additional surgical capacity in Durham County. The proposed project effectively expands capacity to DUH inpatient and ambulatory surgical services. The proposed project is needed to expand access to DUH's well-utilized surgical services."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for four ORs in Durham County and DUHS proposes to develop four ORs in Durham County.
- The applicant adequately demonstrates a projected deficit of ORs at DUH in 2020 through 2024
- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs at DUHS and in Durham County.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services, proposed to be provided.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section Q, Form H, page 125, the applicant provides the projected staffing by number of full time equivalent (FTE) positions for the proposed services, as illustrated in the following table.

Position	Projected FTE Positions		
	PY1 CY2021	PY2 CY2022	PY3 CY2023
Clerical / Registration	3.5	3.5	3.5
RN Supervisor	1.0	1.0	1.0
Surgery RN	23.9	25.0	25.5
Surgical/Central Sterile Tech	9.6	10.1	10.3
Recovery Care RN	4.5	4.8	5.0
Administrator	1.0	1.0	1.0
Assistant Administrator	1.0	1.0	1.0
Materials/Supply Tech	2.0	2.0	2.0
TOTAL	**46.5**	**48.3**	**49.2**

Totals may not sum due to rounding
Source: Section Q Form H, page 121 of the application (upper right-hand corner of page – lower right-hand corner is page 125.

The assumptions and methodology used to project staffing are provided in Section Q, Form H. The applicant states in Section Q, Form H, page 125 (also shown as page 121, in the upper right-hand corner of page) that the project is staffed for four ORs plus two procedure rooms providing services Monday through Friday, with scheduled occurrences of extended stay patients at less than 10% of total. The applicant states that projected staffing is based on Beckers ASC Staffing Statistics. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 72-73, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H.4(b), page 74, the applicant identifies the proposed Medical Director as J. Mack Aldridge, MD. In Exhibit H.4, the applicant provides a letter from Dr. Aldridge indicating a willingness to serve as medical director for the proposed services. In Sections H.4(a) and H.4(c), pages 73-74, the applicant describes its physician recruitment plans. In Exhibit C.4(a), the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new ambulatory surgical ORs at DNP.

In Section Q, Form H Staffing, the applicant provides current and projected staffing for the existing and proposed services, as illustrated in the following table.

DUH Surgical Services Staffing

Position	Current	Projected FTE Positions		
	FY2018	PY1 FY2022	PY2 FY2023	PY3 FY2024
Physician Assistants	7.48	7.48	7.48	7.48
Nursing				
RNs	1,918.29	1,918.29	1,918.29	1,918.29
LPNs	3.23	3.23	3.23	3.23
Aides/Orderlies	489.43	489.43	489.43	489.43
Clerical	8.02	8.02	8.02	8.02
Nurse Manager	31.70	31.70	31.70	31.70
Nurse Practioner	1.90	1.90	1.90	1.90
Laboratory Technicians	1.99	1.99	1.99	1.99
Surgery		-	-	-
RNs	478.16	478.16	478.16	478.16
LPNs	1.60	1.60	1.60	1.60
Technicians	104.29	104.29	104.29	104.29
Clerical	10.42	10.42	10.42	10.42
Aides/Orderlies	40.68	40.68	40.68	40.68
Nurse Practioner	12.59	12.59	12.59	12.59
Nurse Manager	11.69	11.69	11.69	11.69
Perfusionist	25.13	25.13	25.13	25.13
Central Sterile Supply		-	-	-
Technicians	81.44	81.44	81.44	81.44
Clerical	7.12	7.12	7.12	7.12
Administration		-	-	-
Assistant Administrator - SSA	2.00	2.00	2.00	2.00
PSA/Reimbursement	17.07	17.07	17.07	17.07
Other Dept/Unit		-	-	-
Manager	4.00	4.00	4.00	4.00
Clerical	1.42	1.42	1.42	1.42
CRNA	105.07	105.07	105.07	105.07
Anesthesia Technician	42.00	42.00	42.00	42.00
Total	3,406.72	3,406.72	3,406.72	3,406.72

Source: Form H in Section Q of the application.

The applicant states that the projected staffing is based on the current staffing model for surgical services and inpatient nursing services at DUH. On page 67 of the application, the applicant states that the staffing table reflects the entire surgical services program at DUH, and not solely the four proposed additional operating rooms at North Pavilion. The applicant states:

"Further, because the income statement reflects all revenues associated with the inpatient stays, the DUH staffing table also represents all of surgical services and inpatient nursing services for areas that might care for surgical patients. It does not include FTEs for other services utilized by IP and OP surgical patients (such as radiology, lab, physical therapy, etc.)."

The applicant further states that staffing levels are held constant because projected surgical volumes at DUH are not materially different than existing volumes, as some volume is expected to shift to future ambulatory surgical sites not on the DUH license, but part of the DUHS Durham County "health system". The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 68-70, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 70, the applicant identifies the current medical director as Lisa C. Pickett, MD. In Exhibit 2, the applicant provides a letter from Dr. Pickett indicating support for the proposed services. In Section H, page 71, the applicant describes its physician recruitment plans. In Exhibit 12, the applicant provides physician support letters.

In response to written comments submitted during the 30-day public comment period, the applicant states:

"The current tremendous investment in DUH surgical services staffing (greater than 3,406 FTEs) is entirely capable of managing the projected DUH surgical services cases (and surgical hours) during the initial three project years."

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section I, page 76, the applicant states that the following ancillary and support services are necessary for the proposed services:

- patient registration,
- billing,
- medical records,
- housekeeping,
- administration and management services,
- anesthesia,
- radiology,
- pathology, and
- pharmacy consulting.

On page 76, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits A.9 and I.1.

In Section I, pages 76-77, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibits C.4(b) and I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new ambulatory surgical ORs at DNP.

In Section I, page 72, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Administration
- Business office / patient billing
- Medical records
- Professional services (physicians)
- Nursing and Technologists
- Pharmacy
- Medical supplies
- Imaging / Laboratory / Pathology / Anesthesiology
- Materials management / Sterile Processing
- Social Services
- Therapy
- Food and nutrition services
- Housekeeping
- Linen services
- Pastoral care
- Facility maintenance

On page 72, the applicant adequately explains that each ancillary and support service is currently available at DUH and will continue to be made available.

In Section I, pages 73-74, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 12.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and

- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA- Both Applications

Neither of the applicants projects to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, neither of the applicants projects to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA- Both Applications

Neither of the applicants is an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing

health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section K, page 81, the applicant states that the project involves 27,063 square feet of leased space to be occupied by SSC in a shell building occupied by other tenants, who will be physically, operationally and financially separate from SSC. Line drawings are provided in Exhibit K.1. A draft lease agreement is provided in Exhibit K.5.

In Section, K.4, page 82, the applicant explains how the cost, design and means of construction represent the most reasonable alternative for the proposed services.

In Section K.4(b), pages 82-83, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 82-83, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 84-85, the applicant identifies the proposed site and provides information about the current owner and draft lease agreement, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.5.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

In Section K, pages 77-78, the applicant states that the project involves renovation of 2,820 square feet of existing space and the upfitting of 15,606 square feet in the DNP building. Line drawings are provided in Exhibit 7. In addition to adding four new ORs, the applicant will relocate one OR on Level 2 to the newly upfitted space to enable the expansion of the pre-op / post-anesthesia care unit (PACU) to improve workflow and support the new ORs.

On page 79, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposed renovations and provides supporting documentation in Exhibit 7.

On page 79, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Exhibit 7, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C - Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

The proposed ASF is not an existing facility; however, SSC and NCSH have common ownership and SSC will have an operating agreement with Surgery Partners, which operates NCSH, and some surgical cases will shift to the proposed facility from its related entity, NCSH. In Section L, page 88, the applicant provides the historical payor mix during CY2017 for NCSH, and its ORs and procedure rooms, as shown in the table below.

Payor Category	Entire Facility	Operating Rooms	Procedure Rooms
Self-Pay	1.0%	1.0%	2.0%
Charity Care^	0.0%	0.0%	0.0%
Medicare*	47.0%	47.0%	48.0%
Medicaid*	3.0%	3.0%	4.0%
Insurance*	42.0%	42.0%	41.0%
Worker Compensation	5.0%	5.0%	4.0%
TRICARE	2.0%	2.0%	1.0%
Other (specify)	0.0%	0.0%	0.0%
Total	**100.0%**	**100.0%**	**100.0%**

Source: Table L.1(b) on page 88
*Including any managed care plans
^The applicant states that NCSH provided $206,186 (0.34% of total gross revenue) of charity care to ambulatory surgery patients in FY2017 and is reflected in the percentage for self-pay

The information in the table above does not specify whether the payor mix is based on total cases or total revenue; however, in Section L.3(b), page 89, the applicant states that the projected payor mix is based on the 2017 historical percentages for NCHS ambulatory OR and procedure room cases, thus the Project Analyst infers that the percentages here are of total cases.

In Section L, page 87, the applicant provides the following comparison.

	Percentage of Total Patients Served by NCSH	Percentage of the Durham County Population
Female	55.0%	52.3%
65 and Older	45.0%	11.9%
Racial Minorities	32.0%	46.9%

Sources: NCSH Records and US Census Quickfacts.

The applicant does not provide the timeframe for the above information; however, the response is to a question that inquires about medically underserved populations currently using the applicant's services.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

In Section L, page 86, the applicant provides the historical payor mix during FY2018 for the entire DUH facility, and the inpatient and outpatient surgical cases, as summarized in the table below.

Payor Category	Entire Facility IP Days of Care	Inpatient Surgery Cases	Outpatient Surgery Cases	Combined IP/OP Surgery
Self-Pay / Charity Care	2.5%	2.1%	2.4%	2.1%
Medicare*	39.6%	42.5%	34.7%	40.8%
Medicaid*	24.4%	17.8%	9.7%	16.0%
Insurance*	29.4%	31.5%	48.0%	35.2%
Other (specify)**	4.1%	6.2%	5.2%	5.9%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Source: Table L.1(b) on page 86
*Including any managed care plans
**Other includes, Workers comp, TRICARE, and other government

In Section L, page 86, the applicant provides the following comparison.

	Percentage of Total Inpatients Served by DUH during the Last Full FY2018	Percentage of Total Outpatients Served by DUH during the Last Full FY2018	Percentage of the Population of the Service Area: Durham County
Female	45.5%	55.0%	52.2%
Male	54.5%	44.9%	47.8%
Unknown	0.0%	0.1%	0.0%
64 and Younger	61.1%	68.2%	87.3%
65 and Older	38.9%	31.8%	12.7%
American Indian	1.0%	0.5%	0.9%
Asian	1.5%	2.2%	5.2%
Black or African-American	23.4%	22.8%	37.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%	0.1%
White or Caucasian	68.2%	65.8%	42.5%
Other Race	3.7%	4.6%	13.7%
Declined / Unavailable	2.2%	4.0%	0.0%

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C - Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(a), page 88, the applicant states that the proposed facility has no such obligations under applicable federal regulations.

The proposed ASF is not an existing facility; however, SSC and NCSH have common ownership and SSC will have an operating agreement with Surgery Partners, which also operates NCSH, and some surgical cases will shift to the proposed facility from related entity, NCSH.

In Section L.2(c), page 88, the applicant states that during the last five years no patient civil rights access complaints have been filed against NCSH or any similar facilities owned by a related entity and located in North Carolina.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, pages 87-88, the applicant states that DUHS has no obligation under applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons other than those obligations which apply to private, not-for-profit, acute care hospital which participate in Medicare, Medicaid and Title V programs.

On page 88, the applicant states that there were three civil rights access complaints filed against DUHS during the last five years. Two have been closed without further investigation and one is pending a decision.

The Agency reviewed the:

- application,
- exhibits to the application,

- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section L.3(b), page 89, the applicant projects the payor mix for the proposed services during the first three full fiscal years of operation following completion of the project, as shown in the table below.

SSC Proposed Payor Mix
CY2021-CY2023
Percent of Cases

Payor Category	Entire Facility	Operating Rooms	Procedure Rooms
Self-Pay	1.0%	0.7%	1.5%
Charity Care^	0.4%	0.3%	0.5%
Medicare*	47.4%	47.0%	48.0%
Medicaid*	3.4%	3.0%	4.0%
Insurance*	41.6%	42.0%	41.0%
Worker Compensation	4.6%	5.0%	4.0%
TRICARE	1.6%	2.0%	1.0%
Other (specify)	0.0%	0.0%	0.0%
Total	**100.0%**	**100.0%**	**100.0%**

Source: Table L.3(b) on page 89
*Including any managed care plans
^The applicant states that the percentage shown for charity care at SSC is based on the anticipated amount of discounted care (deduction from revenue) to be provided to low income and indigent self-pay patients
Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.7% of the proposed ASF surgical services in ORs will be provided to self-pay patients, 0.3% to charity care patients, 47.0% to Medicare patients and 3.0% to Medicaid patients.

On page 89, the applicant provides the assumptions used to project payor mix for the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- projected payor mix is based on historical NCSH payor percentages for OR and procedure room cases,
- projected payor mix for the facility is based on the combined volumes of OR cases and procedure room cases,
- the applicant expresses a commitment to expand access to healthcare services for the medically underserved in Section C.8, page 48.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

In Section L, page 89, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Proposed Payor Mix
FY2023

Payor Source	Inpatient Surgery Cases	Outpatient Surgery Cases
Self-Pay/Charity Care	2.1%	2.4%
Medicare *	43.7%	35.6%
Medicaid *	17.8%	9.7%
Insurance *	30.4%	47.1%
Other (Workers comp, VA & TRICARE)	6.2%	5.2%
Total	**100.0%**	**100.0%**

* Including any managed care plans
Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects 2.1% of total inpatient surgical services will be provided to self-pay / charity care patients, 43.7% to Medicare patients and 17.8% to Medicaid patients. The applicant projects that 2.4% of total outpatient surgical services will be provided to self-pay / charity care patients, 35.6% to Medicare patients and 9.7% to Medicaid patients.

On page 89, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant based the projected payor mix on historical inpatient and outpatient surgical cases at DUH.
- The applicant adjusted the payor mix to account for the shift of surgical cases from managed care to Medicare for both inpatient and outpatient surgical cases based on the aging population.
- The applicant states that DUH provides surgical services to Medicare and Medicaid recipients, the uninsured and the underinsured, self-pay and commercial pay patients, without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section L.5, page 90, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

In Section L, page 91, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new ambulatory surgical ORs at DNP.

In Section M, page 92, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant states that its existing relationships will assure continuing contact between training and clinical programs at Duke and training programs at other institutions.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C – Both Applications

On page 57, the 2018 SMFP states, *"An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* In Figure 6.1, page 62 of the 2018 SMFP, Durham County is shown as a single-county operating room service area. Thus, in this review, the service area is Durham County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved outpatient, inpatient, and shared operating rooms located in Durham County, and the outpatient and inpatient case volumes for each provider, from pages 65 and 73 of the 2018 SMFP, respectively.

Durham County 2016 Operating Room Inventory and Cases
As Reported in the 2018 SMFP from the 2017 License Renewal Applications

	IP ORs	OP ORs	Shared ORs	Excluded C-Section/ Trauma/Burn ORs	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
James E. Davis Ambulatory Surgical Center (DASC)	0	8	0	0	0		5,164	5
Duke University Hospital	6	9	50	-1	0	17,151	22,642	1
Duke Regional Hospital	2	0	13	-2	0	3,765	2,981	3
Duke University Health System	8	17	63	-3	0			
North Carolina Specialty Hospital	0	0	4	0	0	1,629	3,606	4
Total Durham County ORs	**8**	**17**	**67**	**-3**	**0**			

Source: 2018 SMFP

As the table above indicates, there are three hospitals and one existing or approved ASF in Durham County with a total of eight inpatient, 17 ambulatory and 67 shared operating rooms. Project ID #J-11508-18 was approved for the development of an additional DUHS ASF in Durham County, AASC, by the relocation of four DASC ORs to the proposed facility. Total number of Durham County ORs is not changed by that project.

Table 6B, page 73 of the 2018 SMFP, identifies a need for four additional operating rooms in the Durham County service area.

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section N, pages 92-94, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 92, the applicant states:

"The proposed project will enhance competition to provide greater access to cost-effective ambulatory surgery.

…

As a new alternative provider, Southpoint Surgery center will compete with existing and proposed ambulatory surgery centers in terms of scope of surgical services, quality of care, patient satisfaction, and cost effectiveness.

…

Southpoint Surgery Center is committed to provide excellent quality of surgical service and will be entirely focused on the quality of care related to facility

development in compliance with all requirements, medical staff credentialing, licensure, and accreditation."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

In Section N, pages 93-95, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. Beginning on page 93, the applicant states:

"The proposed operating room expansion project will promote competition in the service area because it will enable DUH to better meet the needs of its existing patient population, and to ensure more timely provision of and convenient access to surgical services for residents of Durham County and surrounding communities.

…

This project will enhance Duke's ability to continue to provide cost-effective and high-quality services to patients.

…

As an existing hospital, DUH has all necessary ancillary and support services in place. Addition of operating rooms represents increased operational economy of scale and efficiency. Therefore, DUH will be able to most cost-effectively increase its OR capacity.

…

DUHS will continue to operate DUH with the highest quality standards. … DUH will maintain the highest standards and quality of care, consistent with the high standard that DUHS has sustained throughout its history of providing surgical care."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C – Both Applications

SSC. The applicant proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms.

In Section O.3, page 97, the applicant identifies the surgical facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three facilities offering surgical services located in North Carolina:

- North Carolina Specialty Hospital in Durham County,
- Orthopaedic Surgery Center of Asheville in Buncombe County, and
- Wilmington SurgCare in New Hanover County.

In Section O.3(b), page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

DUHS. The applicant proposes to add four additional ORs at DUH, License #H0015, for a total of 69 ORs, by developing four new hospital-based ambulatory surgical ORs at DNP.

In Section O.3, page 101, the applicant states that the hospital facilities owned by Duke University Health System include Duke University Hospital and Duke Raleigh Hospital. Duke University Health System also leases and operates Duke Regional Hospital.

In Section O.3(c), page 102, the applicant states:

> *"No Duke hospital has been determined to be out of compliance with any Medicare Conditions of Participation during the 18 months prior to submission of this CON application."*

DUHS also provides surgical services at DASC, a freestanding ASF, in Durham County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all three facilities, the applicant provided

sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C-Both Applications

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C.2100, are applicable to both applications in this review.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

.2101 DEFINITIONS

The following definitions apply to all rules in this Section:

(1) "Approved operating rooms" means those operating rooms that were approved for a certificate of need by the Healthcare Planning and Certificate of Need Section (Agency) prior to the date on which the applicant's proposed project was submitted to the Agency, but that have not been licensed.

(2) "Dedicated C-section operating room" means an operating room as defined in Chapter 6 in the 2018 State Medical Facilities Plan. For purposes of this Section, Chapter 6 in the 2018 State Medical Facilities Plan is hereby incorporated by reference including subsequent amendments and editions. This document is available at no cost at https://www.ncdhhs.gov/dhsr/ncsmfp/index.html.

(3) "Existing operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals that were reported in the Ambulatory Surgical Facility License Renewal Application Form or in the Hospital License Renewal Application Form submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, and that were licensed prior to the beginning of the review period.

(4) "Health System" shall have the same meaning as defined in Chapter 6 in the 2018 State Medical Facilities Plan.
(5) "Operating room" means a room as defined in G.S. 131E-176(18c).
(6) "Operating Room Need Methodology" means the Methodology for Projecting Operating Room Need in Chapter 6 in the 2018 State Medical Facilities Plan.
(7) "Service area" means the Operating Room Service Area as defined in Chapter 6 in the 2018 State Medical Facilities Plan.

.2103 PERFORMANCE STANDARDS

.2103(a) *An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

-C- **SSC.** This proposal would develop four new ORs in an ASF in Durham. The applicant projects sufficient surgical cases and hours to demonstrate the need for the four new ORs at the proposed ASF and the four existing ORs at NCSH in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **DUHS.** This proposal would develop four additional hospital-based ambulatory ORs at DUH, a member of the DUHS Durham County health system. The applicant projects sufficient surgical cases and hours to demonstrate the need for four additional ORs at DUH and in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.2103(b) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-C- **SSC.** In Section Q, Form C Utilization – Assumptions and Methodology, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

-C- **DUHS.** In Section Q, Form C Utilization – Assumptions and Methodology, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2018 State Medical Facilities Plan, no more than four additional operating rooms may be approved for Durham County in this review. The two applications in this review collectively propose to develop eight additional operating rooms to be located in Durham County, however only four ORs can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

The following provides a brief description of each of the proposed projects being addressed in the comparative analysis:

SSC. Southpoint Surgery Center, LLC, Project ID #J-11626-18, proposes to establish a new ASF in Durham County by developing four new ORs and two procedure rooms. The applicant proposes to perform 4,273 total surgical cases in its four ORs in PY3.

DUHS. Duke University Health System, Inc., Project ID #J-11631-18, proposes to add four ORs to the DUH license by developing four additional hospital-based ambulatory ORs at DNP. The applicant proposes to perform 41,088 total surgical cases in its 69 ORs at DUH in PY3.

As the above descriptions of the projects indicate, SSC proposes to develop a four-OR ASF, while DUHS proposes to develop four additional hospital-based ambulatory ORs for a total of 69 ORs at DUH. DUH is an Academic Medical Center offering specialized tertiary and quaternary services and a full continuum of emergency, medical and surgical services. Thus, DUHS projects many times the number of surgeries projected by SSC. Because of the significant differences in types of facilities, numbers of total ORs, numbers of projected surgeries, types of proposed surgical services offered, and the differences in total revenues and expenses, the comparatives may be of less value and result in less than definitive outcomes than if both applications were for like facilities of like size proposing like services.

Conformity with Review Criteria

Table 6C, page 80, of the 2018 SMFP identifies a need for four new ORs in Durham County. As shown in Table 6B, page 73, the only two facilities that show a projected OR deficit (need) in 2020 are Duke University Hospital with a deficit of 5.77 ORs and North Carolina Specialty Hospital, with a deficit of 2.59 ORs. The Duke "Health System" shows a deficit of 1.19 ORs. However, the application process is not limited to the provider (or providers) that show a deficit and create the need for additional ORs. Any provider can apply to develop the four ORs in Durham County. Furthermore, it is not necessary that an existing provider have a deficit of ORs to apply for more ORs. However, it is necessary that an applicant adequately demonstrate the need to develop its project, as proposed.

Both applications adequately demonstrate the need for their respective proposals and are conforming with all applicable statutory and regulatory review criteria. Therefore, generally speaking, the applications are equally effective alternatives with respect to this comparative.

Geographic Accessibility

The existing Durham County ORs (Duke University Hospital, Duke Regional Hospital, James E. Davis Ambulatory Surgical Center (DASC) and North Carolina Specialty Hospital) are located within five miles of each other in the city of Durham. Durham is a city in and the county seat of Durham County. The city is approximately 108 square miles.[1] DUHS has received approval to relocate four of the eight DASC ORs and to develop a new ASF in Triangle Township in southern Durham (Project ID #J-11508-18).

SSC proposes to develop its proposed ASF at 7810 NC 751 Hwy, Durham, in Triangle Township, in southern Durham. DUHS proposes to add four additional hospital-based ORs at Duke North Pavilion, 2400 Pratt Street, Durham, two blocks north of DUH. Both proposals will add four ORs within the Durham city limits. Both the Triangle and Durham Townships have existing and/or approved ambulatory surgical services available. Therefore, with regard to geographic access, generally speaking, the proposals are equally effective.

Physician Support

Each application documents adequate physician support of their proposed projects. Therefore, with regard to the demonstration of physician support, generally speaking, the proposals are equally effective.

Patient Access to New Provider

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

SSC. Southpoint Surgery Center, LLC proposes to develop Southpoint Surgery Center in Durham County. In Section A, page 5 of its application, the applicant states that North Carolina Specialty Hospital, LLC has ownership of SSC. In Section A.9, page 8, the applicant states that SSC will have an operating agreement with Surgery Partners which has ownership in NCSH. Therefore, though SSC will be a new ambulatory surgical facility, created by a new LLC applicant; it will not constitute a new provider of surgical services for Durham County.

DUHS. Duke University Health System, Inc. proposes to add four ORs on the DUH License #H0015, for a total of 69 ORs. DUHS is an existing provider of surgical services in Durham County.

[1] https://en.wikipedia.org/wiki/Durham,_North_Carolina

Neither applicant proposes access to a new provider of surgical services in Durham County. Therefore, with regard to introducing a new provider of surgical services in Durham County, generally speaking, the applications are equally effective.

Patient Access to Multiple Surgical Services

The following table illustrates the surgical specialties (as defined on the North Carolina Hospital License Renewal Application (LRA) that this review's individual CON applicant/owner facilities (NCSH and DUHS) reported on their 2018 LRAs:

Specialty and Related Sub-specialties	NCSH	DUHS
Cardiothoracic, excluding Open Heart		X
Open Heart		X
General Surgery	X	X
Neurosurgery, including Spine Surgery		X
Obstetrics and Gynecology, excluding C-Section	X	X
Ophthalmology	X	X
Oral Surgery /Dental	X	X
Orthopedic, including Spine Surgery	X	X
Otolaryngology (ENT)	X	X
Plastic Surgery	X	X
Podiatry	X	X
Urology		X
Vascular		X
Other (Pediatric)		X

The table above shows the specialties reported by each hospital system, NCSH and DUHS, on its 2018 LRA. DUHS consists of DUH, DRH, and DASC. DUH is an Academic Medical Center (AMC) offering specialized tertiary and quaternary services and a full continuum of emergency, medical and surgical services. In line with that status, DUH reported access to a broader range of specialties than did NCSH. NCSH is not an AMC, is not a tertiary or quaternary hospital, and did not operate a full service emergency department during FY2017.

The following table provides the number of cases by surgical specialty, as reported by the existing Durham County surgical providers on their 2018 LRAs:

FY2017 Surgical Cases by Specialty Performed in Durham County
Excluding C-Sections

	NCSH	DUH	DRH	DASC	Total	Percent of Total
Orthopedic, including Spine Surgery	3,997	7,436	2,760	893	15,086	26.4%
General Surgery	186	6,476	2,079	269	9,010	15.8%
Ophthalmology	344	5,654	78	2,860	8,936	15.6%
Obstetrics and Gynecology, excluding C-Section	12	2,008	1,104	339	3,463	6.1%
Otolaryngology (ENT)	576	2,239	69	539	3,423	6.0%
Cardiothoracic, excluding Open Heart		3,302	9		3,311	5.8%
Neurosurgery, including Spine Surgery		3,032	260		3,292	5.8%
Urology		3,051	181	3	3,235	5.7%
Plastic Surgery	121	2,284	9	111	2,525	4.4%
Podiatry	78	1,252	18		1,348	2.4%
Open Heart		1,173	98		1,271	2.2%
Other (DUH Pediatric Surgery)		1,031		2	1,033	1.8%
Vascular			629	261	890	1.6%
Oral Surgery /Dental	59	243			302	0.5%

Totals may not sum due to rounding
Source: Durham County surgical providers' 2018 LRAs

As the table above shows, of the five most performed specialties (the specialty surgeries composing at least 6% of total surgeries), orthopedic surgery makes up 26.4% of the FY2017 surgery specialties performed in Durham County, followed by 15.8% general surgery, 15.6% ophthalmology, 6.1% obstetrics and gynecology, and 6.0% otolaryngology.

In Section C.1, pages17-18, **SSC** proposes to provide all five of the 2017 most performed specialties in Durham County, along with urology, plastic surgery, vascular and oral surgeries in its proposed ORs. **DUHS** does not specifically list the surgical specialties intended to be provided in its proposed four new ambulatory ORs in its application. As can be seen in the table above, DUH provided all of the above surgical specialties, except vascular surgeries in FY2017, per its 2018 LRA; however, that includes inpatient and outpatient surgeries performed in the hospital, which of course would include some surgeries that would not be appropriate for an ambulatory setting. The actual specialties to be offered in the proposed new ORs at DNP is not clear. Therefore, it is not possible to make conclusive comparisons with regard to surgical specialties. Thus, this comparative factor may be of little value.

Patient Access to Lower Cost Surgical Services

There are currently 92 ORs (including one trauma/burn OR at DUH and two dedicated C-Section ORs at DRH) in the Durham County operating room service area. Operating rooms can be licensed

either under a hospital license or as an ASF that does not operate under a hospital license. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can either be performed in a hospital licensed operating room (either a shared OR or a dedicated outpatient OR) or in a non-hospital licensed operating room or ASF; however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room or ASF. Nonetheless, along with inpatient surgical services, there are some outpatient surgical services that must be performed in a hospital setting; therefore, the need for hospital-based ambulatory surgical services should not automatically be discounted.

The following table identifies the existing and approved Durham County ORs by type of OR.

Facility	Inpatient ORs*	Ambulatory ORs	Shared ORs	CON Adjustments	Total*
James E. Davis Ambulatory Surgical Center (DASC)	0	8	0	0	8
Duke University Hospital	6	9	50	0	65
Duke Regional Hospital (DRH)	2	0	13	0	15
Duke University Health System	8	17	63	0	88
North Carolina Specialty Hospital	0	0	4	0	4
Durham County Total	**8**	**17**	**67**	**0**	**92**

*Total inpatient ORs includes one trauma/burn OR at DUH and two C-Section ORs at DRH

The table above shows that eight of the non-dedicated 89 ORs (excludes one dedicated trauma/burn and two dedicated C-Section ORs), or 9% of the total Durham County ORs are ASF operating rooms. Conversely, 81 or 91% of the total Durham County ORs are either hospital inpatient ORs, hospital shared ORs or hospital dedicated ambulatory ORs.

The following table identifies the number and percent of inpatient and ambulatory surgical cases in Durham County during FY2017.

Ambulatory Surgical Cases as Percent of Total Durham County Surgical Cases

Durham Surgical Facility	Inpatient	Ambulatory (outpatient)	Total	Percent Ambulatory
James E. Davis Ambulatory Surgical Center (DASC)	0	5,277	5,277	100.0%
Duke University Hospital*	17,989	22,575	40,564	55.7%
Duke Regional Hospital (DRH)	4,539	3,352	7,891	42.5%
North Carolina Specialty Hospital	1,649	3,724	5,373	69.3%
Total, including C-Sections	**24,177**	**34,928**	**59,105**	**59.1%**

Source: Durham County surgical providers' 2018 LRAs
*Total line item on DUH LRA is 146 cases higher than the sum total of the individual cases by specialty and is assumed to be an insignificant difference.

As the table above shows, 59.1% of the total Durham County surgical cases in 2017 were performed as ambulatory (outpatient) surgeries. Durham County currently has only one existing ASF, DASC, licensed for eight ambulatory ORs. However, DUHS has been approved to relocate four of the eight DASC ORs and to develop a new ASF, Arringdon Ambulatory Surgical Center (AASC) in southern Durham County (Project ID #J-11508-18). The total number of ASF ORs in Durham County, existing and approved, is currently eight.

Based upon the fact that 59.1% of Durham County's 2017 surgical cases were ambulatory cases and ASF ORs in Durham County compose only 9% of the total OR capacity in Durham County, a project proposing the development of ASF ORs would, generally speaking, be more effective. Thus, this comparative factor may be of little value.

Access by Underserved Groups

Projected Charity Care

The following table shows both applicant's projected self-pay / charity care cases to be provided in the project's third full operating year. Generally, the application proposing to provide the higher percentage of total cases to self-pay /charity care recipients is the more effective alternative with regard to this comparative factor.

Surgical Self-Pay/Charity Care Cases PY3

	Projected Total Cases	Projected Self-pay/Charity Cases	% of Total Cases Projected for Self-Pay/Charity Recipients
SSC	4,273	43	1.0%
DUHS	41,088	926	2.3%

Source: Forms F.4 and F.5 for each applicant.

As shown in the table above, **DUHS** projects more self-pay / charity care surgical cases as a percent of total surgical cases to be provided to patients. Therefore, the application submitted by

Duke University Health System, generally speaking, is the more effective alternative with regard to access to charity care. However, due to the significant differences in the types of facilities, numbers of total ORs, numbers of projected surgeries, types of surgical services offered, and the differences in total revenues and expenses, it is not possible to make conclusive comparisons with regard to Charity Care. Thus, this comparative factors may be of little value.

Projected Medicare

The following table shows both applicant's total number of projected surgical cases and the number of cases projected to be provided to Medicare patients in the applicant's third full year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to serve the higher percent of total surgical cases to Medicare patients is the more effective alternative with regard to this comparative factor.

Surgical Medicare Cases
PY3

	Projected Total Cases	Projected Medicare Cases	% of Total Cases Provided to Medicare Recipients
SSC	4,273	2,008	47.0%
DUHS	41,088	16,295	39.7%

Source: Forms F.4 and F.5 for each applicant.

As shown in the table above, **SSC** projects 47% and **DUHS** projects 39.7% of their surgical cases will be performed on Medicare recipients. Therefore, the application submitted by **Southpoint Surgical Center, LLC**, generally speaking, would be the more effective application with regard to serving Medicare recipients. However, due to the significant differences in the types of facilities, numbers of total ORs, numbers of projected surgeries, types of surgical services offered, and the differences in total revenues and expenses, it is not possible to make conclusive comparisons with regard to Medicare. Thus, this comparative factor may be of little value.

Projected Medicaid

The following table shows both applicant's total number of projected surgical cases and the number of cases projected to be provided to Medicaid patients in the applicant's third full year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to serve the higher percent of total surgical cases to Medicaid patients is the more effective alternative with regard to those comparative factors.

Surgical Medicaid Cases
PY3

	Projected Total Cases	Projected Medicaid Cases	% of Total Cases Provided to Medicare Recipients
SSC	4,273	128	3.0%
DUHS	41,088	5,651	13.8%

Source: Forms F.4 and F.5 for each applicant.

As shown in the table above, **DUHS** projects 13.8% of its surgical cases will be performed on Medicaid recipients, and **SSC** projects 3.0% of its total surgical cases will be Medicaid cases. Therefore, the application submitted by **Duke University Health System**, generally speaking, is the more effective application with regard to serving Medicaid recipients. However, due to the significant differences in the types of facilities, numbers of total ORs, numbers of projected surgeries, types of surgical services offered, and the differences in total revenues and expenses, it is not possible to make conclusive comparisons with regard to Medicaid. Thus, this comparative factors may be of little value.

Projected Average Net Revenue per Case

The following table shows the projected average net surgical revenue per OR and per surgical case in the third year of operation for both applicants, based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing the lower average net revenue is the more effective alternative with regard to this comparative factor.

Surgical Revenue per OR and per Surgical Case
PY3

	Net Revenue	# of ORs*	# of Cases	Net Revenue/OR	Net Revenue/Case
SSC	$13,253,321	4	4,273	$3,313,330	$3,102
DUHS	$885,994,025	69	41,088	$12,840,493	$21,563

Source: Forms F.3, F.4 and F.5 for OR revenue in each application
*Includes one trauma/burn OR at DUH

As shown in the table above, **SSC** projects the lower net revenue per surgical case and per OR in the third operating year. Therefore, the application submitted by **Southpoint Surgery Center, LLC**, generally speaking, would be the more effective application with respect to net revenue. However, due to the significant differences in the types of facilities, numbers of total ORs, numbers of projected surgeries, types of surgical services offered, and the differences in total revenues and expenses, it is not possible to make conclusive comparisons with regard to revenue. Thus, this comparative factors may be of little value.

Projected Average Operating Expense per Case

The following table compares the projected average operating expense in the third year of

operation for both applicants, based on the information provided in the applicants' pro forma financial statements (Form B). Generally, the application proposing the lower average operating expense is the more effective alternative with regard to this comparative factor.

Operating Expense per OR and per Surgical Case
PY3

	Operating Expense	# of ORs*	# of Cases	Operating Expense/OR	Operating Expense/Case
SSC	$14,720,984^	4	4,273	$3,680,246	$3,445
DUHS	$1,091,370,052	69	41,088	$15,816,957	$26,562

Source: Forms F.3 of the individual applications
*Includes one trauma/burn OR at DUH
^ Form F.3 is for the ambulatory surgical facility and includes all operating expenses for the facility

As shown in the table above, **SSC** projects the lower average operating expense per surgical case and per OR in the third operating year. Therefore, the application submitted by **Southpoint Surgery Center, LLC**, generally speaking, would be the more effective application with respect to operating expense. However, due to the significant differences in the types of facilities, numbers of total ORs, numbers of projected surgeries, types of surgical services offered, and the differences in total revenues and expenses, it is not possible to make conclusive comparisons with regard to operating expenses. Thus, this comparative factors may be of little value.

SUMMARY

The following is a summary of the comparative analysis performed on the proposed projects submitted during this review, ranking the effectiveness of the proposals.

Comparative Factor	SSC	DUHS
Conformity with Review Criteria	Equally Effective	Equally Effective
Geographic Accessibility	Equally Effective	Equally Effective
Physician Support	Equally Effective	Equally Effective
Patient Access to New Provider	Equally Effective	Equally Effective
Patient Access to Lower Cost Surgical Services	More Effective	Less Effective
Patient Access to Multiple Services	Inconclusive	Inconclusive
Access by Underserved Groups: Charity Care	Inconclusive	Inconclusive
Access by Underserved Groups: Medicare	Inconclusive	Inconclusive
Access by Underserved Groups: Medicaid	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

As shown in the table above, one factor separates the two applicants: Patient Access to Lower Cost Surgical Services. Thus, it would appear that SSC's application is the most effective alternative in this review. However, pursuant to 10A NCAC 14C .0203, this application cannot be included in the review period beginning December 1, 2018 because the Agency determined that the application was not complete by November 30, 2018, the last working day before the review began. The discussion regarding 10A NCAC 14C .0203 in Criterion (1) is incorporated herein by reference. Therefore, Project ID #J-11626-18 is not approvable in this review.

CONCLUSION

Southpoint Surgery Center, LLC, Project I.D. J-11626-18, cannot be approved in this review period; and thus cannot be an effective alternative. Therefore, the application submitted by **Duke University Health System, Inc., Project I.D. J-11631-18** is the more effective alternative proposed in this review for new operating rooms to be located in Durham County and is therefore conditionally approved.

The application submitted by Duke University Health System, Inc. is approved subject to the following conditions.

1. **Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Duke University Health System, Inc. shall develop no more than four additional ambulatory operating rooms at Duke North Pavilion for a total of no more than 69 operating rooms, including one trauma/burn operating room at Duke University Hospital, License # H0015.**

3. **Upon completion of the project, Duke University Hospital shall be licensed for no more than 69 ORs: seven inpatient ORs (including one trauma/burn OR), 49 shared ORs, and 13 dedicated outpatient ORs.**

4. **Duke University Health System shall be licensed for no more than 92 ORs: 69 at Duke University Hospital (including one trauma/burn OR), 15 at Duke Regional Hospital (including two C-Section ORs), four at James E. Davis Ambulatory Surgical Center, and four at Arringdon Ambulatory Surgical Center, upon completion of Project ID #J-11508-18 (develop a new ASF by relocating four ORs from James E. Davis Ambulatory Surgical Center).**

5. **Duke University Health System, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**

6. **For the first three years of operation following completion of the project, Duke University Health System, Inc. shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from**

the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.

7. **Duke University Health System, Inc. shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**

8. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Duke University Health System, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

    a. **Payor mix for the services authorized in this certificate of need.**
    b. **Utilization of the services authorized in this certificate of need.**
    c. **Revenues and operating costs for the services authorized in this certificate of need.**
    d. **Average gross revenue per unit of service.**
    e. **Average net revenue per unit of service.**
    f. **Average operating cost per unit of service.**

9. **Duke University Health System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**